Screening programmes for developmental dysplasia of the hip in newborn infants (Review)

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[Intervention Review]

Screening programmes for developmental dysplasia of the hip in newborn infants

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ABSTRACT

Background

Uncorrected developmental dysplasia of the hip (DDH) is associated with long term morbidity such as gait abnormalities, chronic pain and degenerative arthritis.

Objectives

To determine the effect of different screening programmes for DDH on the incidence of late presentation of congenital hip dislocation.

Search strategy

Searches were performed in CENTRAL (*The Cochrane Library*), MEDLINE and EMBASE (January 2011) supplemented by searches of clinical trial registries, conference proceedings, cross references and contacting expert informants.

Selection criteria

Randomised, quasi-randomised or cluster trials comparing the effectiveness of screening programmes for DDH.

Data collection and analysis

Three independent review authors assessed study eligibility and quality, and extracted data.

Main results

No study examined the effect of screening (clinical and/or ultrasound) and early treatment versus not screening and later treatment.

One study reported universal ultrasound compared to clinical examination alone did not result in a significant reduction in late diagnosed DDH or surgery but was associated with a significant increase in treatment.

One study reported targeted ultrasound compared to clinical examination alone did not result in a significant reduction in late diagnosed DDH or surgery, with no significant difference in rate of treatment.

Meta-analysis of two studies found universal ultrasound compared to targeted ultrasound did not result in a significant reduction in late diagnosed DDH or surgery. There was heterogeneity between studies reporting the effect on treatment rate.

Meta-analysis of two studies found delayed ultrasound and targeted splinting compared to immediate splinting of infants with unstable (but not dislocated) hips resulted in no significant difference in the rate of late diagnosed DDH. Both studies reported a significant reduction in treatment with use of delayed ultrasound and targeted splinting.

One study reported delayed ultrasound and targeted splinting compared to immediate splinting of infants with mild hip dysplasia on ultrasound resulted in no significant difference in late diagnosed DDH but a significant reduction in treatment. No infants in either group received surgery.

Authors' conclusions

There is insufficient evidence to give clear recommendations for practice. There is inconsistent evidence that universal ultrasound results in a significant increase in treatment compared to the use of targeted ultrasound or clinical examination alone. Neither of the ultrasound strategies have been demonstrated to improve clinical outcomes including late diagnosed DDH and surgery. The studies are substantially underpowered to detect significant differences in the uncommon event of late detected DDH or surgery. For infants with unstable hips or mildly dysplastic hips, use of delayed ultrasound and targeted splinting reduces treatment without significantly increasing the rate of late diagnosed DDH or surgery.

PLAIN LANGUAGE SUMMARY

Screening methods for dislocated or improperly formed hips in newborn infants

The hip joint is a ball and socket joint. Newborns may have hips that are not in their socket (dislocated) or hips that are improperly formed (dysplasia). Risk factors for hip dysplasia include a family history of a similar problem and female infants delivered in the breech position. The hips of most newborns will be examined clinically after birth and during infancy to determine whether they are stable, unstable or dislocated. Screening for hip dysplasia may prevent the need for late treatment, which is associated with long term hip deformity, gait disturbance and arthritis. However, early screening leads to increased treatment. Treatment may be complicated by damage to the hip due to impairment of the blood supply (avascular necrosis).

This review found no studies that compared the benefits and costs of early screening versus not screening for hip problems. Studies that compared the addition of ultrasound to clinical examination reported that when ultrasound was performed on all infants, the rate of treatment increased with no significant difference in rate of late detected dysplasia or surgery. Targeted ultrasound to infants at high risk of hip dysplasia did not significantly increase the rate of treatment but also did not significantly reduce the rate of late detected dysplasia or surgery. It is not possible to give clear recommendations for hip screening of newborn infants from the available evidence.

Where infants are clinically detected as having unstable but not dislocated hips, or are detected on ultrasound to have mild hip dysplasia, there is evidence that delaying treatment by two to eight weeks reduces the need for treatment without a significant increase in late diagnosed dysplasia or surgery.

BACKGROUND

The term developmental dysplasia of the hip (DDH) describes a range of hip abnormalities affecting the newborn in which the femoral head and acetabulum are in improper alignment or grow abnormally, or both (Shipman 2006). Clinical instability of the hip is the traditional hallmark of the disorder, but the definition of DDH also includes hips with radiological abnormalities of the femoral head or acetabulum that may or may not be associated with joint instability (Dezateux 2007). The precise cause of DDH is unknown, with a combination of genetic and environmental influences associated with DDH and hip dislocation including family history, fetal crowding, vaginal delivery, breech presentation and female gender (Sewell 2009). Early screening for DDH has the potential to prevent long term hip dysplasia and arthritis requiring hip replacement.

Description of the condition

The prevalence of DDH varies from 1.6 to 28.5 cases per 1000 live births depending on the definition and the population being studied (Bialik 1999; Dezateux 2007). Most cases of DDH resolve without treatment in the first few months of life (Bialik 1999). However, uncorrected DDH, especially when associated with hip dislocation, is associated with significant long term morbidity including gait abnormalities, chronic pain and premature degenerative arthritis of the hip requiring joint replacement in later life. Up to 94% of adults with untreated congenital dislocation of the hip will have moderate or severe osteoarthritis by the second decade (Cooperman 1983). In the Norwegian Arthroplasty Register, DDH was implicated in 9% of all primary hip replacements and almost one third of hip replacements in people under 65 years (Furnes 2000).

Description of the intervention

Screening programmes for DDH involve clinical examination, ultrasound examination (universal or targeted to high risk groups) or a combination of the two. X-ray screening has been used historically but is rarely used today and will not be covered by this review. Risk factors for DDH that may prompt targeted screening include breech presentation, female gender, a first degree relative with DDH, metatarsus adductus, congenital torticollis, talipes, high birthweight and oligohydramnios (Wynne-Davies 1970; Bache 2002). There are also racial differences in the incidence (Yiv 1997).

Clinical examination involves observation of the infant for limb length discrepancy, thigh fold symmetry and any limitation of abduction. The manoeuvres of Barlow and Ortalani are then carried out. Barlow's test is used to dislocate an unstable but normally located femoral head. Ortalani's test is used to return an already dislocated femoral head to the acetabulum. Each test is considered positive if a 'clunk' or instability is felt as the femoral head dislocates (Barlow) or relocates (Ortalani). Clicks felt during the clinical examination are not considered significant (Bond 1997). One important factor in the success of a clinical screening programme is the experience of the examiner (Bialik 1986; Finne 2008). One large cohort study involving over 20,000 infants missed only two cases of hip dislocation that presented at a late stage (15 and 18 months) (Hadlow 1988). Similar results have been seen in other series (Darmonov 1996; Goss 2002).

A range of ultrasound techniques for detecting newborn DDH have been described (Graf 1980; Harcke 1984; Terjesen 1989). Some methods use a static technique to estimate the degree of femoral head coverage by the acetabulum or the appearance of the hip joint. Other methods ultrasound the hip during a dynamic manoeuvre to visualize any subluxation or dislocation of the femoral head while the joint is under stress. Ultrasound allows the detection of dysplastic hips that are clinically stable (Sucato 1999) and detects more DDH than clinical screening alone (Bialik 1999).

How the intervention might work

Dislocated or dislocatable hips that are identified and treated in the neonatal period show more normal growth radiologically and require less surgical intervention than those diagnosed and treated late (Dunn 1985). These observations have prompted screening programmes for DDH, including the routine ultrasound scanning of every newborn hip in several European countries. The biological rationale for hip adduction therapy is to place the growing hip joint into a correctly located position in order to encourage normal subsequent development (Dezateux 2007; Eastwood 2003).

Why it is important to do this review

There is no clear consensus as to what degree of ultrasound abnormality in a newborn hip should be treated (Woolacott 2005; Dezateux 2007; Roposch 2007). Longitudinal studies of universal hip screening show that 90.4% of hips that are ultrasound positive for DDH in the newborn period become normal without treatment (Bialik 1999), implying that many infants are treated for DDH unnecessarily. An alternative to universal screening is targeted screening in which only infants with risk factors for DDH or abnormal clinical examination are evaluated by ultrasound. Universal hip ultrasound screening has been associated with higher rates of treatment than targeted ultrasound screening, but that treatment is generally shorter and less intrusive (Woolacott 2005). Hip abduction splinting, the most common treatment for early DDH, can lead to complications including avascular necrosis of the femoral head (Gore 1999), femoral nerve palsies, pressure sores and parental anxiety (Dezateux 1995; Gardner 2005).

Despite its widespread use internationally, clear evidence linking DDH screening to a reduction in hip complications is weak (Woolacott 2005; Shipman 2006; Dezateux 2007; Kamath 2007). Studies have failed to demonstrate improvements in either the rate of DDH corrective surgery (Godward 1998) or the rate of late presenting DDH (Kamath 2007) since screening was introduced. Furthermore, a committee established by the US Congress in 2006 to evaluate the effectiveness of DDH screening concluded that there was "insufficient evidence to recommend routine screening for developmental dysplasia of the hip in infants as a means to prevent adverse outcomes" (USPSTF 2006).

Controversy also exists about the best time to screen for DDH. Barlow reported that infants examined late in the first week of life have a lower incidence of DDH than those examined in the early part of the week (Barlow 1962). This suggests a spontaneous resolution of DDH, which has been seen in other observational studies (Bialik 1999).

The aim of this review was to examine the evidence of benefits and harms of different screening methods for DDH.

OBJECTIVES

Primary objective

- To determine the effect of different screening programmes for DDH on the incidence of late presentation (after eight weeks of age) of congenital dislocation of the hip. The different programmes that were compared were no screening, clinical screening and ultrasound screening (universal or targeted) alone or in combination.

Secondary objectives

- To determine the effect of early screening (within first two weeks of life) versus late screening (after two weeks and before six weeks) on the incidence of late presentation of congenital dislocation of the hip.

- To determine in children with unstable hips the effect of the addition of hip ultrasound compared to no ultrasound, combined with either re-examination or orthopaedic treatment, on the incidence of late presentation of congenital dislocation of the hip.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised, quasi-randomised controlled trials and cluster randomised trials comparing the effectiveness of different types of screening programme for developmental dysplasia of the hip (DDH).

Types of participants

All newborn infants, up to six weeks of age, being screened for DDH. Trials enrolling infants with unstable hips on clinical examination were eligible as a separate comparison group.

Types of interventions

Screening programmes for DDH

For all infants (unselected infants):

- clinical examination alone versus no screening;

- universal ultrasound examination alone versus no screening;

- targeted ultrasound examination alone versus no screening;

- targeted ultrasound examination alone versus universal ultrasound examination alone;

- clinical examination alone versus universal ultrasound examination alone;

- clinical examination alone versus targeted ultrasound examination alone;

- clinical examination alone versus clinical examination with universal ultrasound;

- clinical examination alone versus clinical examination with targeted ultrasound;

- clinical examination with targeted ultrasound versus clinical examination with universal ultrasound;

- clinical examination with targeted ultrasound versus universal ultrasound examination alone;

- clinical examination with targeted ultrasound versus targeted ultrasound examination alone;

- clinical examination with universal ultrasound versus universal ultrasound examination alone;

- clinical examination with universal ultrasound versus targeted ultrasound examination alone.

'No screening' meant no clinical hip examination by any method.
'Universal' implied that all infants receive screening.
'Targeted' implied that screening is performed on a subset of infants (usually defined by risk of DDH, for example family history of DDH or female breech birth).
For infants with clinically unstable hips:

- clinical examination alone versus clinical examination with ultrasound to determine treatment;

- specialist (e.g. orthopaedic) review and splinting versus delayed ultrasound and targeted specialist (e.g. orthopaedic) review and splinting;

- specialist (e.g. orthopaedic) review and splinting versus re-examination and targeted specialist (e.g. orthopaedic) review and splinting.

The following comparison was not prespecified.
Infants with mild hip dysplasia on ultrasound:

- treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone.

Types of outcome measures

Primary outcomes

Incidence of late diagnosed DDH (> eight weeks of age diagnosed by either clinical examination, ultrasound or x-ray) for which either medical or surgical intervention was required.

Secondary outcomes

- Any treatment.
- Delayed abduction splinting, after eight weeks of age.
- Open surgery for correction of hip dysplasia.
- Avascular necrosis or osteoarthritis of the hip, at any age.
- Delayed walking, > 18 months of age.
- Limb length discrepancy, at any age.
- Gait abnormality, at any age.
- Chronic hip pain, at any age.
- Hip replacement.

Search methods for identification of studies

See: Cochrane Neonatal Review Group search strategy.
We used the standard search strategy of the Cochrane Neonatal Review Group.

Electronic searches

We included the following electronic databases in the search for clinical trials: Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2010, Issue 1), MEDLINE (1950 to February 2010), EMBASE (1980 to 2010). The US National Institutes of Health Clinical Trials register and Current Controlled Trials registry were searched for ongoing trials and unpublished trials. Search strategies are documented in Appendix 1, Appendix 2 and Appendix 3. There was no language restriction.
We updated the searches of CENTRAL, MEDLINE and EMBASE in January 2011. No additional eligible studies were found.

Searching other resources

In addition, we searched conference abstracts (PSANZ 2000 to 2011, RCPCH , PAS 2000 to 2011 and Pediatric Orthopaedic Society of North America (POSNA) 2008 to 2010) and the cited references from retrieved articles. Abstracts of trials were eligible for inclusion. We contacted expert informants (trial authors).

Data collection and analysis

See: Cochrane Neonatal Review Group standard methods.

Selection of studies

Eligibility of studies for inclusion were assessed independently by all review authors. Abstracts were reviewed and full text obtained for those that appeared to fit eligibility criteria.

Data extraction and management

A data collection form was used to aid extraction of relevant information and data from each included study. Two review authors independently extracted data, compared data and resolved differences by consensus.

Assessment of risk of bias in included studies

The standard methods of the Cochrane Neonatal Review Group were employed. The methodological quality of each trial was reviewed independently by the review authors. Each identified trial was assessed for methodological quality with respect to: a) masking of allocation, b) masking of intervention, c) completeness of follow up, and d) masking of outcome assessment. This information is included in the table 'Characteristics of included studies'.
In addition, the 'Risk of bias' table was completed. The review authors independently assessed the risk of bias for each study using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions, detailed below.
1. Random sequence generation: was the allocation sequence adequately generated?
For each included study, we described the method used to generate the allocation sequence as: low risk (any truly random process for example random number table, computer random number generator); high risk (any non-random process for example odd or even date of birth, hospital or clinic record number); or unclear risk.
2. Allocation concealment: was allocation adequately concealed?
For each included study, we described the method used to conceal the allocation sequence as: low risk (for example telephone or central randomisation, consecutively numbered sealed opaque envelopes); high risk (open random allocation, unsealed or non-opaque envelopes, alternation, date of birth); or unclear risk.
3. Blinding of participants, personnel and outcome assessors: was knowledge of the allocated intervention adequately prevented during the study? At study entry? At the time of outcome assessment?
For each included study, we described the methods used to blind study participants and personnel from knowledge of which intervention a participant received. We assessed the methods as: low risk, high risk or unclear risk for participants; low risk, high risk or unclear risk for study personnel; and low risk, high risk or unclear risk for outcome assessors; and the specific outcomes assessed.
We used the term 'blinding of treatment' to refer to the screening and management pathway. We used the term 'blinding of measurement' to refer to outcome assessment (for example DDH or surgery).

4. Incomplete outcome data: were incomplete outcome data adequately addressed?
For each included study and for each outcome, we described the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. We assessed methods as: adequate (< 20% missing data); inadequate ($\geq$ 20% missing data); or unclear.
5. Selective outcome reporting: are reports of the study free of suggestion of selective outcome reporting?
For each included study, we assessed the possibility of selective outcome reporting bias as: low risk (where it was clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported); high risk (where not all the study's pre-specified outcomes were reported, one or more reported primary outcome was not pre-specified, outcomes of interest were reported incompletely and so cannot be used, study failed to include results of a key outcome that would have been expected to have been reported); or unclear risk.
6. Other sources of bias: was the study apparently free of other problems that could put it at a high risk of bias?
For each included study, we described any important concerns regarding other possible sources of bias (for example whether there was a potential source of bias related to the specific study design or whether the trial was stopped early due to some data-dependent process). We assessed whether each study was free of other problems that could put it at risk of bias as: yes; no; or unclear.

Measures of treatment effect

Effects (95% confidence intervals) were expressed as relative risk (RR), risk difference (RD) and, when statistically significant, number needed to treat (NNT) for categorical data; and mean difference (MD) for continuous data.

Unit of analysis issues

Unit of analysis was the individual infant.

Cluster randomised trials

We planned to include cluster randomised trials in the analyses along with individually randomised trials. We planned to adjust their sample sizes or standard errors using the methods described in the Handbook (Section 16.3.4 or 16.3.6) using an estimate of the intra cluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial, or from a study of a similar population. If we used ICCs from other sources, we planned to report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identified both cluster randomised trials and individually randomised trials, we planned to synthesise the relevant information. We consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and an interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

Dealing with missing data

Authors of included trials were contacted for additional information and data, as required, to ensure data was as up to date as possible. Where data was missing the denominator was reported as those infants in which the outcome was assessed. All analyses were by intention to treat. Sensitivity analysis was conducted including only studies with < 10% losses. We contacted Professor Carol Dezateux, Professor Diana Elbourne, Dr Ketil Holen, and Professor Karen Rosendahl. No additional data were obtained.

Assessment of heterogeneity

Heterogeneity was tested and quantified using the Chi^2 test for heterogeneity for statistical significance and the I^2 statistic to quantify heterogeneity. The degree of heterogeneity was graded as: 0% to 30%, might not be important; 31% to 50%, moderate heterogeneity; 51% to 75%, substantial heterogeneity; 76% to 100%, considerable heterogeneity. If heterogeneity was found, potential reasons were explored using subgroup analysis according to infant risk and screening method; and sensitivity analysis for study quality.

Assessment of reporting biases

Each included study was assessed independently by the two review authors for possible reporting biases. We planned to assess reporting and publication bias by examining the degree of asymmetry of a funnel plot in RevMan 5. Where we suspected reporting bias (see 'Selective reporting bias' above), we planned to contact study authors asking them to provide missing outcome data. We explored the impact of including such studies in the overall assessment of results by a sensitivity analysis.

Data synthesis

Data were entered and analysed in Revman 5. In the absence of heterogeneity, a fixed-effect model was used to pool results and obtain the fixed-effect (FE) RR, weighted MD (WMD) and standardised mean different (SMD), where appropriate. Where heterogeneity was found and data were thought to be appropriate to pool, then a random-effects (RE) model was planned.

Subgroup analysis and investigation of heterogeneity

Subgroup analysis of trials was conducted according to pre-specified criteria in 'Types of interventions' including:

1. trials conducting screening before two weeks versus after two weeks and before six weeks of age;
2. mode of screening (universal or targeted, static or dynamic);
3. severity of abnormality identified at screening (as defined by the trial).

Subgroup analysis was performed on:

1. risk factors for hip abnormality including breech presentation at delivery, gestational age, ethnic group, gender, first degree family history of DDH and associated metatarsus adductus, congenital torticollis, talipes or oligohydramnios;
2. experience or training of examiner (subgroup analysis added post hoc) including:
    i) Experienced paediatrician or orthopaedic surgeon versus doctor or nurse in training;
    ii) Experienced radiologist or ultrasonographer versus doctor or technician in training.

Funnel plots were planned to explore possible publication or other bias.

Sensitivity analysis

Sensitivity analysis was performed to evaluate the effect of trial quality. High quality trials were defined as trials having adequate randomisation and allocation concealment, blinded measurement of outcomes, < 10% losses to follow up and an intention-to-treat analysis.

R E S U L T S

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

Results of the search

The searches located five studies with multiple reports that met the eligibility criteria (see 'Characteristics of included studies' table). A further 10 studies were assessed and excluded after obtaining the published articles. No ongoing studies were identified. The searches of CENTRAL, MEDLINE and EMBASE were last updated in January 2011.

Included studies

Five studies met the eligibility criteria (Gardiner 1990; Rosendahl 1994; Elbourne 2002; Holen 2002; Rosendahl 2010), see table 'Characteristics of included studies'. Two studies (Rosendahl 1994; Holen 2002) compared either clinical examination or targeted ultrasound or universal ultrasound as initial screening for DDH. Two studies (Gardiner 1990; Elbourne 2002) compared clinical examination with early splinting to later hip ultrasound with targeted splinting in infants with clinically unstable hips. One study (Rosendahl 2010) compared immediate splinting to delayed hip ultrasound and targeted splinting in infants with mild hip dysplasia identified on early ultrasound.

Types of infants

Unselected infants: Infants being clinically screened for DDH
Holen 2002 enrolled unselected infants examined clinically on day one. Rosendahl 1994 enrolled unselected infants examined clinically within 24 to 48 hours of delivery.

Infants with unstable hips

Elbourne 2002 enrolled infants under 43 days age with clinically unstable hips diagnosed by a senior doctor. The study excluded infants with previous hip ultrasonographic imaging; infants whose attending clinician was certain immediate splinting was indicated; infants with a hip 'click' but no instability; and infants with risk factors for dislocation but hips clinically normal by the Ortolani-Barlow test. Gardiner 1990 enrolled infants with clinically dislocatable hips. All infants were examined within 24 hours by a junior doctor with the positive findings confirmed by a senior paediatrician. Infants with clinically dislocated hips were splinted immediately and thus excluded, the remaining infants with dislocatable hips were enrolled in the trial.

Infants with mild hip dysplasia on ultrasound

Rosendahl 2010 enrolled term infants with mild dysplasia in one or both hips, identified on hip ultrasound. Ultrasound was undertaken one day after detection of clinical hip instability or the identification of risk factors for DDH (breech presentation at delivery, or first- or second-degree family history of DDH) at the newborn screening examination on day one to three. Exclusion criteria included infants with dislocated, dislocatable, or severely dysplastic hips; infants < 2.5 kg at birth or with major congenital anomalies.

Types of interventions

Unselected infants

1. Clinical examination with universal ultrasound versus clinical examination alone: Rosendahl 1994 allocated infants to clinical examination and universal ultrasound or clinical examination and

no ultrasound. Clinical examination was performed by a doctor with at least two years of paediatric experience (80% qualified paediatrician). Ultrasound was performed within 24 to 48 hours of delivery using the method of Graf and a dynamic ultrasound during a Barlow equivalent maneuver. Infants were treated if the hip was clinically dislocatable, dislocated; they had major dysplastic morphology or minor dysplastic morphology with instability.
2. Clinical examination with targeted ultrasound versus clinical examination: Rosendahl 1994 allocated infants to universal ultrasound, selective ultrasound (if clinical dislocation, dislocatable or instability, breech, close family history of DDH) or no ultrasound. Ultrasound was performed within 24 to 48 hours of delivery using the method of Graf and a dynamic ultrasound during a Barlow equivalent manoeuvre. Infants were treated if the hip was clinically dislocatable, dislocated; they had major dysplastic morphology or minor dysplastic morphology with instability.
3. Clinical examination with universal ultrasound versus clinical examination with targeted ultrasound: Holen 2002 randomised infants to clinical examination and universal ultrasound on or around day three, or to clinical examination and targeted ultrasound. The infants had risk factors (neonatal hip instability, doubtful clinical findings, family history of hip dysplasia, breech position, and foot deformities).

Infants with clinically unstable hips

4. Immediate clinical examination and splinting versus delayed clinical examination and ultrasound with targeted splinting in infants with clinically unstable hips: Elbourne 2002 randomised infants with clinically unstable hips to clinical examination by a specialist with immediate splinting of hips confirmed to be clinically unstable versus ultrasound examination of hips after two weeks and decision to splint based on ultrasound findings. Static and dynamic ultrasound methods of Graf were used with immediate splinting of hips with significant displacement or instability. Infants with minor displacement or instability received ultrasound at eight weeks with splinting if the abnormality persisted. Gardiner 1990 allocated infants with unstable hips to immediate splinting or sonographic surveillance at 10 to 14 days age. Hips that remained clinically unstable or had shown no sonographic improvement were splinted while the remainder of infants continued under sonographic surveillance.

Infants with mild hip dysplasia on ultrasound

5. Immediate splinting versus delayed hip ultrasound and targeted splinting in infants with mild hip dysplasia on ultrasound: Rosendahl 2010 randomised Infants with persistent mild stable hip dysplasia on ultrasound to immediate splinting for at least six weeks using a Frejka pillow splint with sonographic follow up versus active sonographic surveillance but no treatment before six weeks of age.

Types of outcomes measured

Primary outcomes: In Elbourne 2002 the reported primary aim was to assess whether ultrasonography reduced the likelihood of children with neonatal hip instability being splinted without a doubling of the risk of late treatment. Gardiner 1990 did not report a primary outcome. Holen 2002 and Rosendahl 1994 reported late diagnosed hip dysplasia as the primary outcome. Rosendahl 2010 reported incidence of abduction splinting and risk of persistent or more severe dysplasia in later infancy as primary outcomes.

Late diagnosed DDH

Elbourne 2002 defined late diagnosed DDH by radiological appearance of the hips at two years.
Abnormal: dislocation, subluxation, severe dysplasia or avascular necrosis.
Borderline: mild or moderate dysplasia, absent or delayed ossification of the capital femoral epiphysis or suspected avascular necrosis.
Late diagnosed DDH: abnormal and borderline at two years. Gardiner 1990 defined late diagnosed DDH by radiograph taken at six months, repeated at one year in 56% of infants.
Late diagnosed DDH: abnormal radiograph at latest time. Holen 2002 defined late diagnosed DDH as hip dysplasia diagnosed after one month of age on the ultrasonography or radiograph result; including dislocation, subluxation and acetabular dysplasia. Rosendahl 1994 defined late diagnosed DDH by radiographs after one month age; classified as dysplasia, dysplasia with subluxation and dysplasia with dislocation. Rosendahl 2010 defined late diagnosed DDH by radiologic appearance of the hip at one year using the acetabular index (AI): normal (AI within 1 SD), acetabular ossification delay (AI 1 - 2 SD), or dysplasia (AI > 2 SD), according to the classification system used by Tonnis and Brunken.

Excluded studies

Ten studies were assessed and excluded after obtaining the published articles. The studies and reasons for exclusion are reported in the table 'Characteristics of excluded studies'. All were historical control or cohort comparisons of various methods of clinical and ultrasound screening for DDH.

Risk of bias in included studies

See table 'Characteristics of included studies'. Two studies (Elbourne 2002; Rosendahl 2010) reported adequate allocation sequence generation and concealment, and blinding of outcome measures. One of these studies (Elbourne 2002) had a 15% loss of infants for assessment of the primary outcome (late diagnosed DDH) due to radiographs not being available for review. The other studies had substantial methodological concerns.

Allocation

Adequate sequence generation was reported by three studies (Elbourne 2002; Holen 2002; Rosendahl 2010). Two studies used quasi-random methods of patient allocation: Gardiner 1990 alternately allocated infants to groups; Rosendahl 1994 allocated infants to groups according to nursery unit and availability of radiologist.

Adequate allocation concealment was reported by two studies (Elbourne 2002; Rosendahl 2010). Allocation sequence was predictable for two studies (Gardiner 1990; Rosendahl 1994) and was unclear for one study (Holen 2002) as examination occurred before allocation.

Blinding

Treatment: no study reported blinding of treatment. Blinding of screening and treatment is unlikely given the nature of the interventions.

Clinical outcomes: blinding of clinical outcomes to group of allocation was unclear or not blinded in all studies.

Radiological assessment of DDH: four studies (Gardiner 1990; Rosendahl 1994; Elbourne 2002; Rosendahl 2010) reported blinded ultrasound or radiograph assessment of late diagnosed DDH. One study (Holen 2002) did not report efforts to blind radiological assessment of DDH.

Incomplete outcome data

One study reported no losses (Rosendahl 2010), whilst losses were unclear or not adequately addressed for four studies (Gardiner 1990; Rosendahl 1994; Elbourne 2002; Holen 2002). Elbourne 2002 reported 95/629 (15%) radiographs not available for determining incidence of late diagnosed DDH. Gardiner 1990 reported that the 79 infants represented 78% of infants with dislocatable hips diagnosed. In Holen 2002 the rate of incomplete reporting of late diagnosed DDH was unclear although 351/7840 (5%) of the universal screening group did not have ultrasounds. In Rosendahl 1994 the rate of incomplete reporting of late diagnosed DDH was unclear as the study relied on cases being picked up by the National Health System or presenting to a hospital contacted by the author.

Selective reporting

Two studies (Elbourne 2002; Rosendahl 2010) reported prespecified primary outcomes so were free from selective reporting bias. Three studies (Gardiner 1990; Rosendahl 1994; Holen 2002;) did not pre-specify primary outcomes so it is unclear if they were free from selective reporting bias.

Other potential sources of bias

Only one study (Rosendahl 2010) had clear pre-specified methods, including sample size calculation, primary radiographic and clinical outcomes, and so it was clear the study was likely to be free from other types of bias such as multiple interim analyses, premature stopping or multiple endpoint analysis.

Effects of interventions

1. Unselected infants: clinical examination with universal ultrasound versus clinical examination alone

Rosendahl 1994 reported the outcomes of 7537 infants and reported no significant difference in late diagnosed DDH (RR 0.54, 95% CI 0.19 to 1.59), a significant increase in rate of treatment (RR 1.88, 95% CI 1.41 to 2.51; RD 0.01, 95% CI 0.01 to 0.02; NNT 100), and no significant difference in surgery (RR 0.22, 95% CI 0.01 to 4.52) in infants with universal ultrasound compared to those with clinical examination alone. Rates of late diagnosed DDH were 1.4 versus 2.6 per 1000 and rates of treatment were 3.4% versus 1.8% comparing universal ultrasound versus clinical examination. Two infants received surgery, both in the clinical examination group.

Subgroup analyses

Rosendahl 1994 was eligible for the following subgroup analyses.

- Timing of screening, before two weeks of age.
- Mode of screening:
  - universal ultrasound versus clinical examination;
  - ultrasound included static and dynamic measurements.
- Severity of abnormality: requiring treatment defined as clinically dislocatable or dislocated hips; or on ultrasound if dislocatable, dislocated, major dysplastic morphology, or minor dysplastic morphology with instability.
- Experience of examiner: clinical examination performed by doctor with at least two years of paediatric experience (80% qualified paediatrician).
- Experience of ultrasonographer: performed by single physician.

Sensitivity analysis

Rosendahl 1994 was not eligible for inclusion in sensitivity analysis due to non-random allocation sequence.

2. Unselected infants: clinical examination with targeted ultrasound versus clinical examination alone

Rosendahl 1994 reported the outcomes of 8312 infants and reported no significant difference in late diagnosed DDH (RR 0.80, 95% CI 0.33 to 1.98), no significant difference in rate of treatment (RR 1.12, 95% CI 0.82 to 1.53), and no significant difference in surgery (RR 0.45, 95% CI 0.04 to 4.93) in infants with targeted ultrasound compared to those with clinical examination alone. Rates of treatment were 2.0% versus 1.8% comparing targeted ultrasound versus clinical examination. Two infants received surgery in the clinical examination group versus one in the clinical examination and targeted ultrasound group.

Subgroup analyses

Rosendahl 1994 was eligible for the following subgroup analyses.

- Timing of screening: before two weeks age.
- Mode of screening:
  - targeted ultrasound versus clinical examination;
  - ultrasound included static and dynamic measurements.
- Risk factors for hip abnormality: selective ultrasound group included infants with clinical dislocation, dislocatability or instability, breech delivery or close family history of DDH (at least one first degree relative or two second degree relatives).
- Severity of abnormality: requiring treatment defined as clinically dislocatable or dislocated hips; or on ultrasound if dislocatable, dislocated, major dysplastic morphology, or minor dysplastic morphology with instability.
- Experience of examiner: clinical examination performed by doctor with at least two years of paediatric experience (80% qualified paediatrician).
- Experience of ultrasonographer: performed by single physician.

Sensitivity analysis

Rosendahl 1994 was not eligible for inclusion in sensitivity analysis due to non-random allocation sequence.

3. Unselected infants: clinical examination with universal ultrasound versus clinical examination with targeted ultrasound

Meta-analysis of two studies (Holen 2002; Rosendahl 1994) reporting outcomes of 23,530 infants found no significant difference in late diagnosed DDH (FE RR 0.49, 95% CI 0.19 to 1.26) in infants with universal ultrasound compared to those with targeted ultrasound.

There was significant (P = 0.04) and substantial heterogeneity (I^2 = 77%) between studies reporting rate of treatment. Rosendahl 1994 reported a significant increase in treatment (RR 1.68, 95% CI 1.28 to 2.20) in infants with universal ultrasound and Holen 2002 reported no significant difference (RR 1.07, 95% CI 0.77 to 1.49). In the subgroup analyses below, differences that could potentially explain the heterogeneity of treatment included different treatment thresholds and differences in the experience of the clinical hip examiners. In sensitivity analysis, both studies had substantial methodological concerns. Meta-analysis was not considered appropriate for treatment rate in view of study heterogeneity and study differences.

Meta-analysis of two studies (Holen 2002; Rosendahl 1994) reporting outcomes of 23,530 infants found no significant difference in surgery (fixed-effect model RR 0.36, 95% CI 0.04 to 3.48) in infants with universal ultrasound compared to those with targeted ultrasound. Holen 2002 assessed the outcomes of 15,529 infants and reported no significant difference in delayed abduction splinting (RR 0.25, 95% CI 0.03 to 2.19). Meta-analysis of two studies found no significant difference in avascular necrosis or osteoarthritis (fixed-effect model RR 0.33, 0.01 to 8.02). Rates of treatment were 1.7% versus 1.3% comparing universal versus targeted ultrasound. One infant developed avascular necrosis in the targeted ultrasound group. Two infants received surgery, both in the targeted ultrasound group. There was no significant heterogeneity for other analyses.

Subgroup analyses

The following subgroup analyses were performed.

- Timing of screening: both studies screened infants before two weeks age.
- Mode of screening:
  - both studies compared universal ultrasound versus targeted ultrasound;
  - both studies included static and dynamic ultrasound measurements.
- Risk factors for hip abnormality: both studies performed targeted ultrasound for similar risk factors and clinical hip examination findings. Holen 2002 targeted ultrasound performed on infants with neonatal hip instability, doubtful clinical findings, family history of hip dysplasia, breech position and foot deformities. Rosendahl 1994 targeted ultrasound performed on infants with clinical dislocation, dislocatability or instability, breech delivery or close family history of DDH (at least one first degree relative or two second degree relatives).
- Severity of abnormality: both studies treated infants with clinical hip instability and hip dysplasia on ultrasound. Holen 2002 treated infants with minor dysplastic morphology whereas Rosendahl 1994 treated infants with minor dysplastic morphology and hip instability.
- Experience of examiner: both studies used experienced examiners for hip examination, either a senior paediatrician (Holen 2002) or doctors with at least two years of paediatric experience (80% qualified paediatrician) (Rosendahl 1994).

- Experience of ultrasonographer: both studies used experienced ultrasonographers, either an orthopaedic specialist (Holen 2002) or a single physician (Rosendahl 1994).

Sensitivity analysis

Rosendahl 1994 was not eligible for inclusion in the sensitivity analysis due to non-random allocation sequence generation. Holen 2002 was not eligible for inclusion in the sensitivity analysis due to unclear allocation concealment and unclear blinding of outcome.

4. Infants with clinically unstable hips: treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone

Meta-analysis of two studies (Elbourne 2002; Gardiner 1990) reporting outcomes of 708 infants found no significant difference in late diagnosed DDH (fixed-effect model RR 1.05, 95% CI 0.60 to 1.85), but a significant reduction in treatment (fixed-effect model RR 0.70, 95% CI 0.59 to 0.82; RD -0.17, 95% CI -0.24 to -0.10; NNT 5.9) in infants with delayed clinical examination and ultrasound compared to those with immediate splinting. Elbourne 2002 reported no significant difference in delayed abduction splinting (RR 1.38, 95% CI 0.56 to 3.38), avascular necrosis or osteoarthritis (RR 1.29, 95% CI 0.49 to 3.42), surgery (RR 0.84, 95% CI 0.48 to 1.47), or delayed walking (RR 0.25, 95% CI 0.03 to 2.23). Surgery was performed in 6.7% versus 7.9% of infants comparing delayed clinical examination and ultrasound versus immediate splinting.

There was significant (P = 0.0002) and considerable heterogeneity (I^2 = 93%) between the studies reporting rate of treatment although both studies reported a significant decrease in treatment. Elbourne 2002 reported a significant decrease in treatment (RR 0.79, 95% CI 0.67 to 0.95) in infants with delayed clinical examination and ultrasound; Gardiner 1990 also reported a significant decrease in treatment (RR 0.30, 95% CI 0.18 to 0.49). There was no significant heterogeneity for the other analysis (late diagnosed DDH). Subgroup analysis suggested that heterogeneity was potentially due to differences either in the time of enrolment or treatment criteria for the clinical examination and immediate splinting group between the studies. Gardiner 1990 enrolled infants immediately after the newborn examination. In Elbourne 2002 ultrasound was performed in multiple centres with the experience of ultrasonographers not documented. Elbourne 2002 did not immediately splint infants with minor instability. Sensitivity analysis suggested differences may be due to methodological differences between studies with only one study having an adequate allocation sequence (Elbourne 2002).

Subgroup analyses

The following subgroup analyses were performed.

- Timing of screening: Gardiner 1990 enrolled infants after newborn examination. Elbourne 2002 enrolled infants before 43 days (62% before 14 days).
- Mode of screening:
  - both studies included static and dynamic ultrasound measurements.
- Severity of abnormality: both studies enrolled infants with clinical hip instability. Both studies excluded infants with clinically dislocated hips. Elbourne 2002 did not immediately treat infants with hips that had minor instability. Gardiner 1990 treated all infants with hip instability immediately.
- Experience of examiner: both studies used experienced doctors for clinical examination.
- Experience of ultrasonographer: the studies differed in their use of ultrasonographers as Gardiner 1990 used a single experienced physician; Elbourne 2002 used ultrasound performed in multiple centres but did not report the experience of the ultrasound technicians although the ultrasound was supported by standardised education and protocols.

Sensitivity analysis

Gardiner 1990 was not eligible for inclusion in the sensitivity analysis due to non-random allocation sequence. Elbourne 2002 was not eligible for inclusion in the sensitivity analysis due to excess losses to follow up (15% not assessed for the primary outcome).

5. Infants with mild hip dysplasia on ultrasound: treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone

Rosendahl 2010 reported outcomes of 128 infants and reported no significant difference in late diagnosed DDH (RR 0.57, 95% CI 0.18 to 1.86), but a significant decrease in treatment (RR 0.46, 95% CI 0.35 to 0.60; RD -0.55, 95% CI -0.67 to -0.42; NNT 1.8) in infants with immediate splinting compared to delayed hip ultrasound and targeted splinting. No infant received surgery in either group.

Subgroup analyses

Rosendahl 2010 was eligible for the following subgroup analyses.

- Timing of screening: enrolled infants before two weeks age.
- Mode of screening:
  - included static and dynamic ultrasound measurements.
- Severity of abnormality: enrolled infants with minor hip dysplasia on ultrasound.
- Experience of examiner: used experienced doctors for clinical examination.
- Experience of ultrasonographer: used experienced ultrasonographers, one of three senior radiologists.

Sensitivity analysis

Rosendahl 2010 was eligible for inclusion in the sensitivity analysis with adequate sequence generation, blinding of outcome assessment and no losses reported.

DISCUSSION

Summary of main results

For all infants (unselected infants)

One study reported that the use of universal ultrasound compared to clinical examination alone did not result in a significant reduction in late diagnosed DDH or surgery but was associated with a significant increase in treatment (3.4% versus 1.8%) of infants for hip abnormalities. Although rates of late diagnosed DDH (1.4 versus 2.6 per 1000) and surgery (0 versus 0.5 per 1000) were not significantly different, the single study reporting this comparison is likely to be underpowered given the low rate of events.

One study reported that the use of targeted ultrasound compared to clinical examination alone did not result in a significant reduction in late diagnosed DDH or surgery. There was no significant difference in treatment (2.0% versus 1.8%) of infants for hip abnormalities. Although rates of late diagnosed DDH (2.1 versus 2.6 per 1000) and surgery (0.2 versus 0.5 per 1000) were not significantly different, the single study reporting this comparison is likely to be underpowered given the low rate of events.

Meta-analysis of two studies found the use of universal ultrasound compared to targeted ultrasound did not result in a significant reduction in late diagnosed DDH or surgery. There was heterogeneity in the findings of studies reporting effect on treatment rate, with one study reporting a significant increase and the other no significant difference, from the use of universal compared to targeted ultrasound. Although rates of late diagnosed DDH (0.5 versus 1.2 per 1000), avascular necrosis (0 versus 0.2 per 1000) and surgery (0 versus 0.1 per 1000) were not significantly different, the analysis of the studies reporting this comparison are likely to be underpowered given the low rate of events.

For infants with clinically unstable hips

Meta-analysis of two studies found the use of delayed ultrasound and targeted splinting compared to immediate splinting of infants with unstable but not dislocated hips resulted in no significant difference in rates of late diagnosed DDH (6.5% versus 6.2%) but a significant reduction in abduction splinting treatment (38.9% versus 56%). In addition, one study reported no significant difference in delayed abduction splinting (3.5% versus 2.5%), avascular necrosis (2.9% versus 2.2%) and surgery (6.7% versus 7.9%).

For infants with mild hip dysplasia on ultrasound

One study reported that delayed hip ultrasound and targeted splinting compared to immediate splinting in infants with mild hip dysplasia on ultrasound resulted in no significant difference in late diagnosed DDH (6.3% versus 10.9%) but a significant reduction in treatment (45.3% versus 100%). No infants in either group received surgery.

Overall completeness and applicability of evidence

For all infants (unselected infants)

No study compared clinical examination versus no screening, or ultrasound screening versus no screening. No conclusion can be made about the balance of benefits and harms from newborn screening for DDH compared to not screening for DDH. Of concern is that screening leads to increased intervention, which has been associated with the development of avascular necrosis (AVN); with the frequency of AVN ranging from 5% to 60% after surgical treatment and 0% to 14% after non-surgical treatment (Shipman 2006).

Evidence to date relates to the addition of universal or targeted ultrasound to clinical examination for the early detection of DDH. The two studies were single centre studies in which the clinical examinations were performed by examiners with substantial paediatric experience and the ultrasound was performed by either experienced orthopedic surgeons (Holen 2002) or a single physician (Rosendahl 1994). The evidence may not be applicable to centres who use doctors or nurses in training to perform the hip examination, or centres in which the hip ultrasound component is performed by multiple sonographers. The studies used both static and dynamic methods of ultrasound examination. Holen 2002 used the static method described by Terjesen and Holen (percentage acetabular cover of femoral head: normal > 47% boys; > 44% girls) and a subjective dynamic test for instability. Rosendahl 1994 used the method of Graf (major dysplastic morphology = Graf types IIIa or worse; mild dysplastic morphology = IIc and D) and a dynamic test performed during a Barlow equivalent manoeuvre. A review of studies of diagnostic accuracy for ultrasound screening (Rosendahl 2007) found that studies reported adequate repeatability for the static [Graf, Morin, modified Morin (Terjesen)] and for the combined static and dynamic methods [modified Graf (Rosendahl)], while no such reports were found for the dynamic (Harcke) ultrasound techniques, suggesting that the methods used in the studies included in this review are likely to have adequate repeatability. Given that both studies used experienced clinical examiners, it is possible that the benefits of ultrasound screening found were less than would have occurred in a setting where doctors or nurses in training are used to perform the clinical examination. It may also be difficult for many care settings to reproduce the outcomes of the ultrasound screened groups given the experience of the ultrasonographers used.

Compared to clinical examination alone, Rosendahl 1994 reported that the use of universal ultrasound significantly increased the rate of treatment for DDH without a significant reduction in rate of late diagnosed DDH or surgery. Use of targeted ultrasound did not significantly affect the rate of treatment, late diagnosed DDH or surgery. Two studies reported heterogeneous effects of universal ultrasound compared to targeted ultrasound on treatment rate, but found no significant differences in rates of late diagnosed DDH, delayed abduction splinting, avascular necrosis or surgery. Although these comparisons include several thousand infants, they are likely to be substantially underpowered to detect important differences in rates of late diagnosed DDH, avascular necrosis and surgery. To detect a fall in rate of late diagnosed DDH from 2.6 to 1.4 per 1000 would require a trial substantially in excess of 100,000 infants.

The two studies comparing the addition of hip ultrasound versus clinical examination alone reported ultrasound or radiological outcomes after one month of age (Holen 2002) or a mean age of 4.5 months (range 2.5 to 18 months) (Rosendahl 1994). Neither study reported longer term functional outcomes of infants. No quality of life scale was reported. Infants with DDH are at risk of long term hip dysplasia, arthritis and functional impairment as well as associated psychological effects. However, the incidence of DDH diagnosed by ultrasound ranges between 34·0 and 60·3 per 1000 and is substantially greater than that detected by Ortolani and Barlow manoeuvres (between 1·6 to 28·5 per 1000). The incidence of DDH detected by imaging is also substantially higher than the prevalence of persistent and clinically diagnosed hip dysplasia in unscreened populations, which is estimated to be 1·3 per 1000 (range 0·84 to 1·5) (Leck 2000). Also, a proportion of infants with unrecognised hip dysplasia (11% to 44%) who present late remain pain free into adulthood (Dezateux 2007). As a result, the studies included in this review are likely to have reported higher rates of late diagnosed DDH than will be reflected in clinical functional outcomes.

For infants with clinically unstable hips

The two included studies enrolled infants with clinically unstable hips. Both excluded infants with dislocated hips (which were splinted immediately) so the findings of the review do not apply to these infants. In the clinical treatment group, infants with clinically unstable hips were splinted and those with minor instability were observed for eight weeks. In the delayed treatment group, infants were reviewed after 10 to 14 days by both clinical and ultrasound investigation. Infants with persisting instability were then splinted, but in one study those with minor instability were monitored for eight weeks. Clinical examination was performed by an experienced paediatrician. Ultrasounds were performed by an experienced sonographer (one of the researchers). The outcomes of 708 infants were reported. Both studies reported rates of late diagnosed DDH (that is persistent clinical or ultrasound abnormality) and rate of treatment, but only one study enrolling 629 infants reported rates of delayed abduction splinting, avascular necrosis and surgery. Late diagnosed DDH was reported at one year by both studies. In addition, Elbourne 2002 reported independent mobility at two years. Longer term hip dysplasia, arthritis and functional impairment, as well as associated psychological effects, were not reported. The findings largely relate to the addition of ultrasound in order to delay and reduce intervention for clinically unstable but not dislocated hips and report functional findings to two years.

For infants with mild hip dysplasia

One study that enrolled 128 infants with mild hip dysplasia on ultrasound reported the effect of immediate splinting compared to delayed ultrasound and targeted splinting at eight weeks. Initial ultrasound was undertaken after either the detection of clinical hip instability or the identification of other risk factors for DDH (breech presentation at delivery, or first or second degree family history of DDH) at the newborn screening examination. Infants with dislocated, dislocatable, or severely dysplastic hips were excluded and received immediate treatment. Infants < 2.5 kg at birth or with major congenital anomalies were also excluded. Late hip dysplasia was reported at one year but longer term hip dysplasia, arthritis and functional impairment as well as associated psychological effects were not reported. This study pertains to the management of mild hip dysplasia in infants with clinically stable hips.

Quality of the evidence

For all infants

Both studies assessing the effects of clinical examination or ultrasound screening, or both, for hip abnormality had substantial methodological concerns, although the allocation methods of one of these studies (Rosendahl 1994) place it at particularly high risk of bias. There is also substantial concern in that for most analyses only a single study is included. Given the low rate of major adverse outcomes, including avascular necrosis, surgery and late diagnosed DDH, there is substantial concern that the analyses are underpowered to detect even a moderate difference between groups. Although Holen 2002 used an adequate method of screening allocation, the allocation concealment was unclear and blinding of outcome assessments was not reported. According to the nursery of admission, Rosendahl 1994 had an inadequate method of infant allocation, and outcome assessment was blinded. There was significant heterogeneity between the studies in rates of treatment comparing infants screened by universal versus targeted ultrasound. Subgroup analyses and sensitivity analysis identified several potential explanations for heterogeneity, including differences in treatment thresholds and differences in the experience of the clinical hip examiners. There are also substantial methodological concerns for both studies.

For infants with clinically unstable hips

The largest study (Elbourne 2002) enrolling 629 infants had adequate infant allocation procedures and blinding of outcome assessment. However, radiographs were not available for 15% of infants at two years. The other small study alternately assigned infants to groups although outcome assessment was reported to be blinded to the group of assignment. There was significant heterogeneity between studies reporting rates of treatment. Subgroup analysis suggests heterogeneity is potentially due to differences either in the time of enrolment or treatment criteria for the clinical examination and immediate splinting group. Sensitivity analysis suggests differences may be due to methodological differences between studies, with only one study having an adequate allocation sequence (Elbourne 2002).

For infants with mild hip dysplasia on ultrasound

The single study, enrolling 128 infants, had no substantial methodological concerns, with adequate sequence generation, blinding of outcome assessment and no losses reported. However, reproducibility of this study's findings is yet to be demonstrated.

Potential biases in the review process

This review included pre-specified study eligibility criteria, quality appraisal criteria and outcomes for assessment of studies and the effects of the interventions. The search strategy included searches for published and unpublished literature, including databases of clinical trials, conference abstracts and expert informants. The appraisal of study eligibility and quality, and extraction of data, were performed independently by three review authors.

The inclusion of studies using quasi-random methods of patient allocation has the potential to bias the findings of the review. In addition, the primary outcome of the review (late diagnosed DDH) is reported for all studies and not restricted to studies of adequate methodology. Risk of bias assessment suggests that there are substantial methodological concerns particularly for the comparisons assessing the effect of clinical hip examination and hip ultrasound for screening of all infants.

Agreements and disagreements with other studies or reviews

The American Association of Pediatrics (AAP) in 2000 recommended that all newborns' hips should be screened by physical examination with examination of all infants' hips according to a periodicity schedule and follow until walking (AAP 2000). The US Preventative Services Task Force (USPSTF) stated "There is evidence that screening leads to earlier identification; however, 60% to 80% of the hips of newborns identified as abnormal or as suspicious for DDH by physical examination and > 90% of those identified by ultrasound in the newborn period resolve spontaneously, requiring no intervention. There is poor evidence (poor quality studies) of the effectiveness of both surgical and non-surgical interventions; avascular necrosis of the hip (AVN) is reported in 0% to 60% of children who are treated for DDH. Thus, the USPSTF was unable to assess the balance of benefits and harms of screening for DDH but was concerned about the potential harms associated with treatment of infants identified by routine screening" (USPSTF 2006). The findings of this review are largely in keeping with these statements, although the USPSTF report also included diagnostic test accuracy assessments and observational studies of infant hip screening outcomes.

It was noted in the USPSTF review (USPSTF 2006) that trials of screening versus not screening are now unlikely to be conducted given the creep of evidence and practice, despite concerns regarding the potential harm from screening and excess treatment. It is probable that research will now focus on reducing rates of treatment in infants with a clinical or ultrasound abnormality, as well as reducing the potential for harm from splinting or other surgical treatment.

AUTHORS' CONCLUSIONS

Implications for practice

It is not possible to give clear recommendations for practice. There were no studies examining the benefits and harms of screening and early treatment versus not screening and later treatment. When screening is used, there is inconsistent evidence that universal ultrasound results in a significant increase in treatment compared to the use of targeted ultrasound or clinical examination alone. Neither ultrasound strategy has been demonstrated to improve clinical outcomes, including late diagnosed DDH and surgery. The studies are substantially underpowered to detect significant differences in the uncommon event of late detected DDH or surgery. The studies included in this review largely used experienced clinical hip examiners and experienced ultrasonographers, with well developed protocols for screening and treatment.

Implications for research

A large trial of ultrasound screening versus clinical screening, either at birth or during infant health checks, is required to determine whether the benefits and costs of early detection and treatment of DDH using ultrasound is superior to clinical examination alone.

For the trial to detect a clinically important difference in functional outcomes, in excess of 100,000 infants are likely to be needed to be enrolled. Consideration should be given to the feasibility of a cluster randomised trial to answer this important question.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Elbourne 2002

Methods	Multicentre randomised controlled trial.
Participants	629 participants under 43 days age with clinically unstable hips as diagnosed by senior doctor Excluded: babies with previous ultrasonographic imaging of hips; those whom attending clinician was certain immediate splinting was indicated; those with a hip click, but no signs of instability; and babies with recognised risk factors for dislocation but whose hips deemed clinically normal by the Ortolani-Barlow test
Interventions	Intervention (ultrasonography group; n = 314): ultrasound examination of hips, aged >2 weeks. Initial decision to splint based on ultrasound findings. Static (method of Graf) and dynamic (method of Harcke) ultrasound views used. Significant displacement and instability treated. Minor displacement or instability received ultrasound monitoring to 8 weeks age. If abnormality persisted at 8 weeks hip splinted Control (non-ultrasonography group; n=315): initial management on basis of clinical findings alone. Unstable hips on specialist examination splinted. Hips with suspicious examination monitored to 8 weeks. Splinted at 8 weeks if abnormality persisted. Follow up could include ultrasound examination after splinting had taken place
Outcomes	Primary outcome: radiological appearance of hips at 2 years. Abnormal: dislocation, subluxation, severe dysplasia or avascular necrosis. Borderline: mild or moderate dysplasia or suspected avascular necrosis. Late diagnosed DDH = abnormal and borderline at 2 years Secondary outcomes: independent mobility at 1 year; presence of avascular necrosis; surgical treatment; resource use and costs. Surgical treatment included: any of open reduction, osteotomy, closed reduction, adductor tenotomy, examination under anaesthetic and arthrogram
Notes	Funded by UK Department of Health through the MRC. 33 health centres from the UK and Ireland chosen to participate in study in order to allow generalisation to the UK NHS (selection criteria not specified). Local research ethics committees approved studies

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Allocation by telephone central randomisation service that allocated babies (after providing clinical details) to either intervention or control group using minimisation (with probabilistic element) to ensure key prognostic factors balanced within groups

Elbourne 2002 (*Continued)*

Allocation concealment (selection bias)	Low risk	
Blinding (performance bias and detection bias) Treatment	High risk	Unable to be blinded.
Blinding (performance bias and detection bias) All clinical outcomes	High risk	Unable to be blinded.
Blinding (performance bias and detection bias) Radiological assessment of DDH	Low risk	Radiographs were assessed by radiologists who were unaware of the diagnostic group to which the patient had been assigned
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	95 (15%) loss to follow up (primarily radiographs not available for review)
Selective reporting (reporting bias)	Low risk	Reported pre-specified primary and secondary outcomes.
Other bias	Unclear risk	Complicated screening protocol.

Gardiner 1990

Methods	Quasi-random: alternately allocated to intervention or control
Participants	Infants with clinically dislocatable hips diagnosed at birth. Infants initially examined within 24 hours by junior doctor and confirmed by senior paediatrician Exclusions: Hips that were dislocated were immediately splinted and were not included in the study
Interventions	Infants with clinically unstable hips had a screening ultrasound and clinical examination then allocated to: 1. Control: immediate splinting (group A, n=41) or 2. Treatment: sonographic surveillance: seen at 10-14 days age - hips re-examined clinically and sonographically. Hips that remained clinically unstable or had shown no sonographic improvement were splinted at this time, while the remainder continued under sonographic surveillance. Hips graded according to Graf (IIc-IV abnormal)
Outcomes	Infants had a pelvic anteroposterior radiograph taken at 6 months. Radiographs were assessed blind to the randomisation. Repeated at 1 year in 56 % of infants, including all those without ossified epiphyses at 6 months. Late diagnosed DDH: abnormal radiograph at latest time (1 year)
Notes	Financial support from Southmead Hospital Research Fund, and the Van Neste Foundation

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Used alternation.
Allocation concealment (selection bias)	High risk	Allocation sequence predictable.
Blinding (performance bias and detection bias) Treatment	High risk	Unable to blind.
Blinding (performance bias and detection bias) All clinical outcomes	Unclear risk	Not reported.
Blinding (performance bias and detection bias) Radiological assessment of DDH	Low risk	Radiographs were assessed blind to the randomisation.
Incomplete outcome data (attrition bias) All outcomes	High risk	79 reported infants represent 78% of infants with dislocatable hips diagnosed
Selective reporting (reporting bias)	Unclear risk	Unclear primary and secondary outcomes.
Other bias	Unclear risk	Complicated screening and management pathway.

Holen 2002

Methods	Single centre, randomised controlled trial.
Participants	All infants (n=15529) born in the University Hospital of Trondheim (Norway) between 1988-1992 Exclusions: residents outside county; parental refusal.
Interventions	All infants examined by a senior paediatrician on day 1 of life for clinical hip instability, and then: Intervention (n=7840): universal ultrasound screening of the hip performed on or around 3 days of life Control (n=7689): targeted ultrasound in infants with risk factors (neonatal hip instability, doubtful clinical findings, family history of hip dysplasia, breech position and foot deformities) Ultrasound method used static method described by Terjesen and Holen (%acetabular cover femoral head - normal >47% boys; >44% girls) and a subjective dynamic test for instability. Ultrasound performed by orthopaedic surgeon along with hip examination All infants with clinical hip instability and or femoral head cover below borderline level treated. In last 2 years study, treatment delayed 2 weeks to infants with persistent clinical

	instability or abnormal hip US
Outcomes	Primary outcome: late detected hip dysplasia diagnosed >1 month of age based on ultrasonography/radiograph results, including dislocation, subluxation and acetabular dysplasia Secondary outcomes: surgery, avascular necrosis.
Notes	Information given on sample size calculation. No financial benefit gained by any authors/ participants

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Allocation by random sampling numbers.
Allocation concealment (selection bias)	Unclear risk	Clinical examination of all infants occurred before randomisation to treatment groups
Blinding (performance bias and detection bias) Treatment	Unclear risk	Unclear whether ultrasonographers were blinded to allocation
Blinding (performance bias and detection bias) All clinical outcomes	Unclear risk	Not reported.
Blinding (performance bias and detection bias) Radiological assessment of DDH	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	351 (5%) of universal screening group did not receive ultrasounds (NICU, deaths, early discharge) - no late DDH found in this group. All hospitals in Norway involved in treating late DDH were checked for possible study participants
Selective reporting (reporting bias)	Unclear risk	Unclear prespecified outcomes.

Rosendahl 1994

Methods	Single centre, quasi-randomised controlled trial.
Participants	11925 infants born Jan 1988-June 1990 born at Maternity Hospital at University of Bergen (Norway) Exclusions: Infants born <1500g; severe malformation.

Interventions	All infants received clinical examination within 24-48 hours of delivery by doctor with at least 2 years Paediatric experience (80% qualified Paediatrician) and frequent clinical exam in infancy All infants with breech or family history of DDH received hip radiograph at 4-5 months Group 1 (n=3613): universal ultrasound. Group 2 (n=4388): selective ultrasound (if clinical dislocation, dislocatable or instability, breech, close family history of DDH) Group 3 (n=3924): no ultrasound. Ultrasound used method of Graf and a dynamic ultrasound during a Barlow equivalent manoeuvre - major dysplastic morphology = Graf types IIIa or worse; mild dysplastic morphology = IIc and D; Infants treated if clinically dislocatable, dislocated, major dysplastic morphology, or minor dysplastic morphology with instability
Outcomes	Primary outcome: Late discovered cases of DDH (after the first month of life) within the area covered by the hospital. As part of the national health program infants included in the study were examined clinically at frequent intervals during the first 2 years of life. Anteroposterior radiographs of the hip joints were evaluated according to Tonnis. Based on the acetabular angle and the position of the femoral head, the late cases were classified as dysplasia, dysplasia with subluxation, and dysplasia with dislocation. Radiologist blinded to allocation. All infants with breech or family history of DDH received hip radiograph at 4-5 months
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Group 3 allocated when radiologist not available for ultrasonography. Groups 1 and 2 determined by bed allocation into adjacent nursery units
Allocation concealment (selection bias)	High risk	Allocation groups determined by bed in nursery unit.
Blinding (performance bias and detection bias) Treatment	Unclear risk	Staff at the delivery unit were unaware of the ongoing trial. Physician doing ultrasound unaware of infant history or clinical findings - unclear as to whether blinded to treatment group
Blinding (performance bias and detection bias) All clinical outcomes	Unclear risk	Not reported.

Rosendahl 1994 (*Continued)*

Blinding (performance bias and detection bias) Radiological assessment of DDH	Low risk	Late cases classified without knowledge of ultrasound.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The diagnosis of late DDH relied on the case being picked up by the national health system and presenting to either the treatment hospital or the other Norwegian hospitals that were contacted by the author
Selective reporting (reporting bias)	Unclear risk	Unclear pre-specified outcomes.
Other bias	High risk	More babies born by caesarean section than expected in universal ultrasound group as this nursery used for infants of postsurgical mothers. It is unclear whether the different physicians (with differing experience levels) performed examinations equally across the different groups. Unclear whether intervention led to increased surveillance for DDH Unbalanced denominators in all 3 arms.

Rosendahl 2010

Methods	Single centre, randomised controlled trial
Participants	Inclusions: Healthy term newborns born at the maternity unit at Haukeland University Hospital, Bergen, Norway, from February 1998 - April 2003 with mild hip dysplasia in 1 or both hips (128 infants) identified on hip ultrasound. Ultrasound undertaken after either the detection of clinical hip instability or the identification of other risk factors for DDH (breech presentation at delivery, or first- or second-degree family history of DDH) at the newborn screening examination Exclusions: Infants with dislocated, dislocatable, or severely dysplastic hips, infants weighing <2.5kg at birth, major congenital anomalies, parental consent not given
Interventions	Infants with persistent mild stable dysplasia were then randomly assigned to receive either: 1. immediate abduction splinting treatment for at least 6 weeks using a Frejka pillow splint with sonographic follow-up (immediate treatment group), or 2. active sonographic surveillance but no treatment before 6 weeks of age (active sonographic-surveillance group) Hip morphology and stability were assessed using a modified Graf technique to measure acetabular angle (normal >60°, immature - 50°-60°, mildly dysplastic 43°-50° or severely dysplastic <43°). Hip stability was assessed sonographically by performing a maneuver similar to the Barlow test

Outcomes	Primary outcome: radiologic appearance of the hip at the end of the first year of life. Used acetabular index (AI) classified as normal (AI within 1 SD), acetabular ossification delay (AI 1-2 SD), or dysplasia (AI >2 SD), according to the classification system used by Tonnis and Brunken Other outcomes: Duration abduction treatment. Persistent hip subluxation or dislocation at 1 year
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation as single block using computerized random-number generator, and group assignments were put in opaque, sealed, and numbered envelopes
Allocation concealment (selection bias)	Low risk	With parent present but the radiologist absent, a senior nurse opened the envelopes in numerical sequence for each infant at the outpatient clinic
Blinding (performance bias and detection bias) Treatment	High risk	
Blinding (performance bias and detection bias) All clinical outcomes	High risk	Reported parents unblinded.
Blinding (performance bias and detection bias) Radiological assessment of DDH	Low risk	Radiologists were blinded to the intervention assigned.
Incomplete outcome data (attrition bias) All outcomes	Low risk	No losses.
Selective reporting (reporting bias)	Low risk	Pre-specified outcome.
Other bias	Low risk	Single primary radiological and single clinical outcome.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Bache 2002	Observational study of universal ultrasound screening for DDH. No control group
Baronciani 1997	Observational cohort of clinical examination and universal ultrasound screening for DDH
Bloomfield 2003	Report on trial comparing clinical examination by senior house officers to clinical examination by trained midwives
Clegg 1999	Historical control study of effect on costs of clinical examination versus universal ultrasound for screening for DDH
Finnbogason 2008	Observational study comparing neonatal hip instability as assessed by dynamic ultrasound and clinical examination with acetabular morphology as assessed by Graf's method
Geitung 1996	Cost effectiveness analysis of cost of hip screening using published data
Glazener 1999	Randomised trial of one screen policy-one neonatal screening examination on day 3 or day before expected discharge if earlier; or two screen policy-one screening examination within 36 hours of birth and a second on the day of discharge or on the day before expected discharge if after day 3
Roovers 2005	Historical control study of clinical versus universal ultrasound
Rosendahl 1992a	Cohort study of clinical examination and targeted ultrasound in newborns
Rosendahl 1992b	Cohort study of clinical examination and targeted ultrasound in newborns

DATA AND ANALYSES

Comparison 1. Unselected infants: Clinical examination with universal ultrasound versus clinical examination alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Late diagnosed DDH	1	7537	Risk Ratio (M-H, Fixed, 95% CI)	0.54 [0.19, 1.59]
2 Any treatment	1	7537	Risk Ratio (M-H, Fixed, 95% CI)	1.88 [1.41, 2.51]
3 Surgery	1	7537	Risk Ratio (M-H, Fixed, 95% CI)	0.22 [0.01, 4.52]

Comparison 2. Unselected infants: Clinical examination with targeted ultrasound versus clinical examination alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Late diagnosed DDH	1	8312	Risk Ratio (M-H, Fixed, 95% CI)	0.80 [0.33, 1.98]
2 Any treatment	1	8312	Risk Ratio (M-H, Fixed, 95% CI)	1.12 [0.82, 1.53]
3 Surgery	1	8312	Risk Ratio (M-H, Fixed, 95% CI)	0.45 [0.04, 4.93]

Comparison 3. Unselected infants: Clinical examination with universal ultrasound versus clinical examination with targeted ultrasound

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Late diagnosed DDH	2	23530	Risk Ratio (M-H, Fixed, 95% CI)	0.49 [0.19, 1.26]
2 Any treatment	2		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
3 Delayed abduction splinting	1	15529	Risk Ratio (M-H, Fixed, 95% CI)	0.25 [0.03, 2.19]
4 Avascular necrosis or osteoarthritis	2	23530	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.01, 8.02]
5 Surgery	2	23530	Risk Ratio (M-H, Fixed, 95% CI)	0.36 [0.04, 3.48]

Comparison 4. Infants with clinically unstable hips: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Late diagnosed DDH	2	708	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.60, 1.85]
2 Any treatment	2	708	Risk Ratio (M-H, Fixed, 95% CI)	0.70 [0.59, 0.82]
3 Delayed abduction splinting	1	629	Risk Ratio (M-H, Fixed, 95% CI)	1.38 [0.56, 3.38]
4 Avascular necrosis or osteoarthritis	1	629	Risk Ratio (M-H, Fixed, 95% CI)	1.29 [0.49, 3.42]
5 Surgery	1	629	Risk Ratio (M-H, Fixed, 95% CI)	0.84 [0.48, 1.47]
6 Delayed walking	1	629	Risk Ratio (M-H, Fixed, 95% CI)	0.25 [0.03, 2.23]

Comparison 5. Infants with mild hip dysplasia on ultrasound: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Late diagnosed DDH	1	128	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.18, 1.86]
2 Surgery	1	128	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Any treatment	1	128	Risk Ratio (M-H, Fixed, 95% CI)	0.46 [0.35, 0.60]

Analysis 1.1. Comparison 1 Unselected infants: Clinical examination with universal ultrasound versus clinical examination alone, Outcome 1 Late diagnosed DDH.

Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 1 Unselected infants: Clinical examination with universal ultrasound versus clinical examination alone

Outcome: 1 Late diagnosed DDH

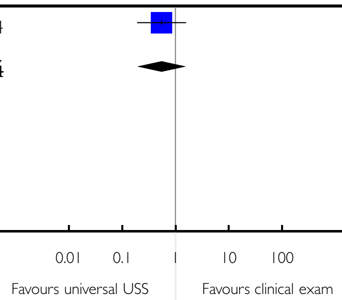
Study or subgroup	Universal USS n/N	Clinical examination n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Rosendahl 1994	5/3613	10/3924		100.0 %	0.54 [0.19, 1.59]
Total (95% CI)	**3613**	**3924**		**100.0 %**	**0.54 [0.19, 1.59]**

Total events: 5 (Universal USS), 10 (Clinical examination)

Heterogeneity: not applicable

Test for overall effect: Z = 1.12 (P = 0.26)

Test for subgroup differences: Not applicable



Analysis 1.2. Comparison 1 Unselected infants: Clinical examination with universal ultrasound versus clinical examination alone, Outcome 2 Any treatment.

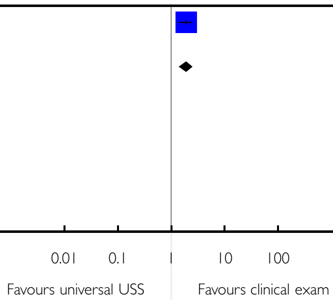
Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 1 Unselected infants: Clinical examination with universal ultrasound versus clinical examination alone

Outcome: 2 Any treatment

Study or subgroup	Universal USS n/N	Clinical examination n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Rosendahl 1994	123/3613	71/3924		100.0 %	1.88 [1.41, 2.51]
Total (95% CI)	**3613**	**3924**		**100.0 %**	**1.88 [1.41, 2.51]**

Total events: 123 (Universal USS), 71 (Clinical examination)
Heterogeneity: not applicable
Test for overall effect: Z = 4.29 (P = 0.000018)
Test for subgroup differences: Not applicable



Analysis 1.3. Comparison 1 Unselected infants: Clinical examination with universal ultrasound versus clinical examination alone, Outcome 3 Surgery.

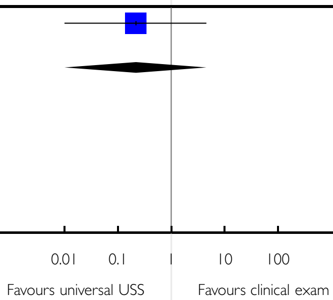
Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 1 Unselected infants: Clinical examination with universal ultrasound versus clinical examination alone

Outcome: 3 Surgery

Study or subgroup	Universal USS n/N	Clinical examination n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Rosendahl 1994	0/3613	2/3924		100.0 %	0.22 [0.01, 4.52]
Total (95% CI)	**3613**	**3924**		**100.0 %**	**0.22 [0.01, 4.52]**

Total events: 0 (Universal USS), 2 (Clinical examination)
Heterogeneity: not applicable
Test for overall effect: Z = 0.99 (P = 0.32)
Test for subgroup differences: Not applicable

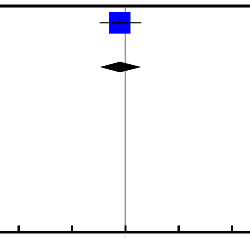


Analysis 2.1. Comparison 2 Unselected infants: Clinical examination with targeted ultrasound versus clinical examination alone, Outcome 1 Late diagnosed DDH.

Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 2 Unselected infants: Clinical examination with targeted ultrasound versus clinical examination alone

Outcome: 1 Late diagnosed DDH

Study or subgroup	Targeted ultrasound n/N	Clinical examination n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Rosendahl 1994	9/4388	10/3924		100.0 %	0.80 [0.33, 1.98]
Total (95% CI)	**4388**	**3924**		**100.0 %**	**0.80 [0.33, 1.98]**

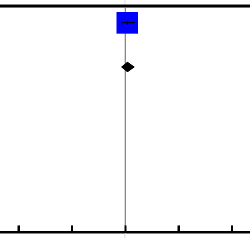
Total events: 9 (Targeted ultrasound), 10 (Clinical examination)
Heterogeneity: not applicable
Test for overall effect: Z = 0.47 (P = 0.64)
Test for subgroup differences: Not applicable

Analysis 2.2. Comparison 2 Unselected infants: Clinical examination with targeted ultrasound versus clinical examination alone, Outcome 2 Any treatment.

Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 2 Unselected infants: Clinical examination with targeted ultrasound versus clinical examination alone

Outcome: 2 Any treatment

Study or subgroup	Targeted ultrasound n/N	Clinical examination n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Rosendahl 1994	89/4388	71/3924		100.0 %	1.12 [0.82, 1.53]
Total (95% CI)	**4388**	**3924**		**100.0 %**	**1.12 [0.82, 1.53]**

Total events: 89 (Targeted ultrasound), 71 (Clinical examination)
Heterogeneity: not applicable
Test for overall effect: Z = 0.72 (P = 0.47)
Test for subgroup differences: Not applicable

Analysis 2.3. Comparison 2 Unselected infants: Clinical examination with targeted ultrasound versus clinical examination alone, Outcome 3 Surgery.

Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 2 Unselected infants: Clinical examination with targeted ultrasound versus clinical examination alone

Outcome: 3 Surgery

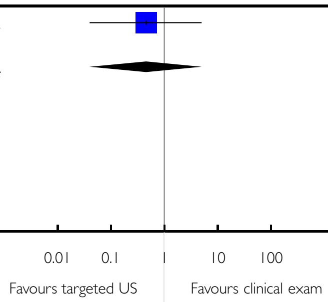
Study or subgroup	Targeted ultrasound n/N	Clinical examination n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Rosendahl 1994	1/4388	2/3924		100.0 %	0.45 [0.04, 4.93]
Total (95% CI)	**4388**	**3924**		**100.0 %**	**0.45 [0.04, 4.93]**

Total events: 1 (Targeted ultrasound), 2 (Clinical examination)

Heterogeneity: not applicable

Test for overall effect: Z = 0.66 (P = 0.51)

Test for subgroup differences: Not applicable



Analysis 3.1. Comparison 3 Unselected infants: Clinical examination with universal ultrasound versus clinical examination with targeted ultrasound, Outcome 1 Late diagnosed DDH.

Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 3 Unselected infants: Clinical examination with universal ultrasound versus clinical examination with targeted ultrasound

Outcome: 1 Late diagnosed DDH

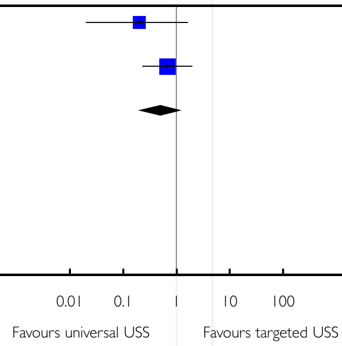
Study or subgroup	Universal USS n/N	Targeted USS n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Holen 2002	1/7840	5/7689		38.3 %	0.20 [0.02, 1.68]
Rosendahl 1994	5/3613	9/4388		61.7 %	0.67 [0.23, 2.01]
Total (95% CI)	**11453**	**12077**		**100.0 %**	**0.49 [0.19, 1.26]**

Total events: 6 (Universal USS), 14 (Targeted USS)

Heterogeneity: $Chi^2 = 1.03$, df = 1 (P = 0.31); $I^2 = 3\%$

Test for overall effect: Z = 1.47 (P = 0.14)

Test for subgroup differences: Not applicable



Analysis 3.2. Comparison 3 Unselected infants: Clinical examination with universal ultrasound versus clinical examination with targeted ultrasound, Outcome 2 Any treatment.

Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 3 Unselected infants: Clinical examination with universal ultrasound versus clinical examination with targeted ultrasound

Outcome: 2 Any treatment

Study or subgroup	Universal USS n/N	Targeted USS n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
Holen 2002	72/7840	66/7689		1.07 [0.77, 1.49]
Rosendahl 1994	123/3613	89/4388		1.68 [1.28, 2.20]

0.01 0.1 1 10 100

Favours universal US Favours targeted US

Analysis 3.3. Comparison 3 Unselected infants: Clinical examination with universal ultrasound versus clinical examination with targeted ultrasound, Outcome 3 Delayed abduction splinting.

Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 3 Unselected infants: Clinical examination with universal ultrasound versus clinical examination with targeted ultrasound

Outcome: 3 Delayed abduction splinting

Study or subgroup	Universal USS n/N	Targeted USS n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Holen 2002	1/7840	4/7689		100.0 %	0.25 [0.03, 2.19]
Total (95% CI)	**7840**	**7689**		**100.0 %**	**0.25 [0.03, 2.19]**

Total events: 1 (Universal USS), 4 (Targeted USS)

Heterogeneity: not applicable

Test for overall effect: Z = 1.26 (P = 0.21)

Test for subgroup differences: Not applicable

0.01 0.1 1 10 100

Favours universal US Favours targeted US

Analysis 3.4. Comparison 3 Unselected infants: Clinical examination with universal ultrasound versus clinical examination with targeted ultrasound, Outcome 4 Avascular necrosis or osteoarthritis.

Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 3 Unselected infants: Clinical examination with universal ultrasound versus clinical examination with targeted ultrasound

Outcome: 4 Avascular necrosis or osteoarthritis

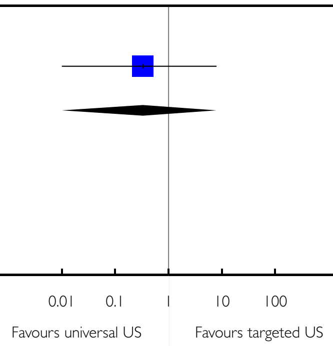
Study or subgroup	Universal USS n/N	Targeted USS n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
Rosendahl 1994	0/3613	0/4388		0.0 [0.0, 0.0]
Holen 2002	0/7840	1/7689		0.33 [0.01, 8.02]
Total (95% CI)	**11453**	**12077**		**0.33 [0.01, 8.02]**

Total events: 0 (Universal USS), 1 (Targeted USS)

Heterogeneity: $Chi^2 = 0.0$, df = 0 (P = 1.00); $I^2 = 0.0\%$

Test for overall effect: Z = 0.68 (P = 0.49)

Test for subgroup differences: Not applicable



Analysis 3.5. Comparison 3 Unselected infants: Clinical examination with universal ultrasound versus clinical examination with targeted ultrasound, Outcome 5 Surgery.

Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 3 Unselected infants: Clinical examination with universal ultrasound versus clinical examination with targeted ultrasound

Outcome: 5 Surgery

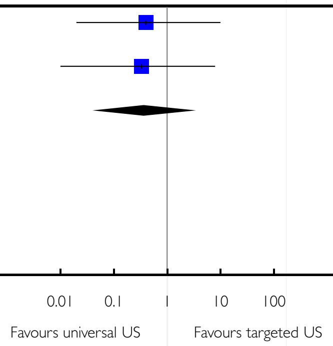
Study or subgroup	Universal USS n/N	Targeted USS n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Rosendahl 1994	0/3613	1/4388		47.2 %	0.40 [0.02, 9.93]
Holen 2002	0/7840	1/7689		52.8 %	0.33 [0.01, 8.02]
Total (95% CI)	**11453**	**12077**		**100.0 %**	**0.36 [0.04, 3.48]**

Total events: 0 (Universal USS), 2 (Targeted USS)

Heterogeneity: $Chi^2 = 0.01$, df = 1 (P = 0.93); $I^2 = 0.0\%$

Test for overall effect: Z = 0.88 (P = 0.38)

Test for subgroup differences: Not applicable



Analysis 4.1. Comparison 4 Infants with clinically unstable hips: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone, Outcome 1 Late diagnosed DDH.

Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 4 Infants with clinically unstable hips: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone

Outcome: 1 Late diagnosed DDH

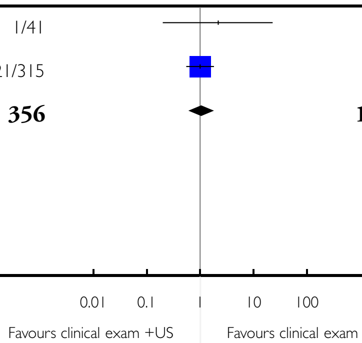
Study or subgroup	Clinical exam +ultrasound n/N	Clinical exam alone n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Gardiner 1990	2/38	1/41		4.4 %	2.16 [0.20, 22.84]
Elbourne 2002	21/314	21/315		95.6 %	1.00 [0.56, 1.80]
Total (95% CI)	**352**	**356**		**100.0 %**	**1.05 [0.60, 1.85]**

Total events: 23 (Clinical exam +ultrasound), 22 (Clinical exam alone)

Heterogeneity: $Chi^2 = 0.38$, df = 1 (P = 0.54); $I^2 = 0.0\%$

Test for overall effect: Z = 0.18 (P = 0.86)

Test for subgroup differences: Not applicable



Analysis 4.2. Comparison 4 Infants with clinically unstable hips: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone, Outcome 2 Any treatment.

Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 4 Infants with clinically unstable hips: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone

Outcome: 2 Any treatment

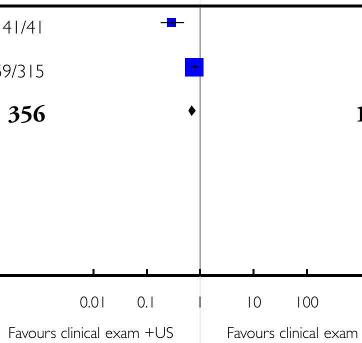
Study or subgroup	Clinical exam +ultrasound n/N	Clinical exam alone n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Gardiner 1990	11/38	41/41		20.1 %	0.30 [0.18, 0.49]
Elbourne 2002	126/314	159/315		79.9 %	0.79 [0.67, 0.95]
Total (95% CI)	**352**	**356**		**100.0 %**	**0.70 [0.59, 0.82]**

Total events: 137 (Clinical exam +ultrasound), 200 (Clinical exam alone)

Heterogeneity: $Chi^2 = 13.90$, df = 1 (P = 0.00019); $I^2 = 93\%$

Test for overall effect: Z = 4.41 (P = 0.000011)

Test for subgroup differences: Not applicable



Analysis 4.3. Comparison 4 Infants with clinically unstable hips: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone, Outcome 3 Delayed abduction splinting.

Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 4 Infants with clinically unstable hips: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone

Outcome: 3 Delayed abduction splinting

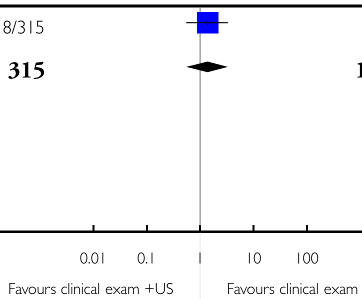
Study or subgroup	Clinical exam +ultrasound n/N	Clinical exam alone n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Elbourne 2002	11/314	8/315		100.0 %	1.38 [0.56, 3.38]
Total (95% CI)	**314**	**315**		**100.0 %**	**1.38 [0.56, 3.38]**

Total events: 11 (Clinical exam +ultrasound), 8 (Clinical exam alone)

Heterogeneity: not applicable

Test for overall effect: Z = 0.70 (P = 0.48)

Test for subgroup differences: Not applicable



Analysis 4.4. Comparison 4 Infants with clinically unstable hips: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone, Outcome 4 Avascular necrosis or osteoarthritis.

Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 4 Infants with clinically unstable hips: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone

Outcome: 4 Avascular necrosis or osteoarthritis

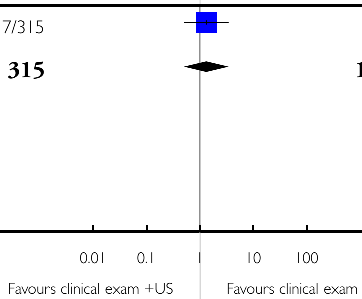
Study or subgroup	Clinical exam +ultrasound n/N	Clinical exam alone n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Elbourne 2002	9/314	7/315		100.0 %	1.29 [0.49, 3.42]
Total (95% CI)	**314**	**315**		**100.0 %**	**1.29 [0.49, 3.42]**

Total events: 9 (Clinical exam +ultrasound), 7 (Clinical exam alone)

Heterogeneity: not applicable

Test for overall effect: Z = 0.51 (P = 0.61)

Test for subgroup differences: Not applicable



Analysis 4.5. Comparison 4 Infants with clinically unstable hips: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone, Outcome 5 Surgery.

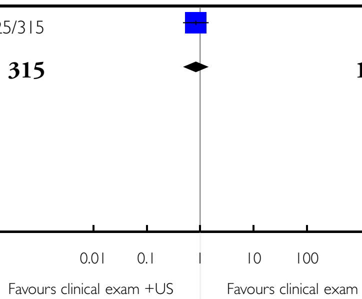
Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 4 Infants with clinically unstable hips: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone

Outcome: 5 Surgery

Study or subgroup	Clinical exam +ultrasound n/N	Clinical exam alone n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Elbourne 2002	21/314	25/315		100.0 %	0.84 [0.48, 1.47]
Total (95% CI)	**314**	**315**		**100.0 %**	**0.84 [0.48, 1.47]**

Total events: 21 (Clinical exam +ultrasound), 25 (Clinical exam alone)
Heterogeneity: not applicable
Test for overall effect: Z = 0.60 (P = 0.55)
Test for subgroup differences: Not applicable



Analysis 4.6. Comparison 4 Infants with clinically unstable hips: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone, Outcome 6 Delayed walking.

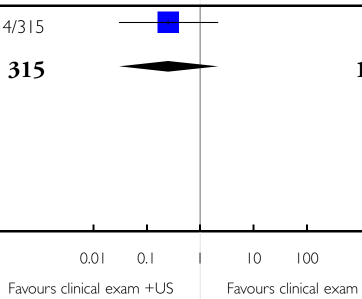
Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 4 Infants with clinically unstable hips: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone

Outcome: 6 Delayed walking

Study or subgroup	Clinical exam +ultrasound n/N	Clinical exam alone n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Elbourne 2002	1/314	4/315		100.0 %	0.25 [0.03, 2.23]
Total (95% CI)	**314**	**315**		**100.0 %**	**0.25 [0.03, 2.23]**

Total events: 1 (Clinical exam +ultrasound), 4 (Clinical exam alone)
Heterogeneity: not applicable
Test for overall effect: Z = 1.24 (P = 0.21)
Test for subgroup differences: Not applicable



Analysis 5.1. Comparison 5 Infants with mild hip dysplasia on ultrasound: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone, Outcome 1 Late diagnosed DDH.

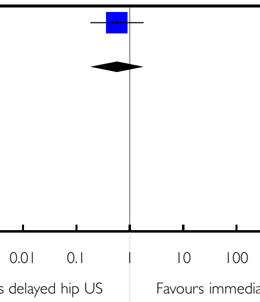
Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 5 Infants with mild hip dysplasia on ultrasound: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone

Outcome: 1 Late diagnosed DDH

Study or subgroup	Delayed hip US n/N	Immediate splinting n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Rosendahl 2010	4/64	7/64		100.0 %	0.57 [0.18, 1.86]
Total (95% CI)	**64**	**64**		**100.0 %**	**0.57 [0.18, 1.86]**

Total events: 4 (Delayed hip US), 7 (Immediate splinting)
Heterogeneity: not applicable
Test for overall effect: Z = 0.93 (P = 0.35)
Test for subgroup differences: Not applicable



Analysis 5.2. Comparison 5 Infants with mild hip dysplasia on ultrasound: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone, Outcome 2 Surgery.

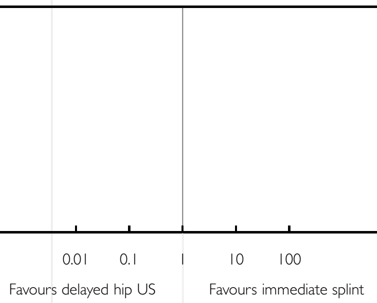
Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 5 Infants with mild hip dysplasia on ultrasound: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone

Outcome: 2 Surgery

Study or subgroup	Delayed hip US n/N	Immediate splinting n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
Rosendahl 2010	0/64	0/64		0.0 [0.0, 0.0]
Total (95% CI)	**64**	**64**		**0.0 [0.0, 0.0]**

Total events: 0 (Delayed hip US), 0 (Immediate splinting)
Heterogeneity: not applicable
Test for overall effect: Z = 0.0 (P < 0.00001)
Test for subgroup differences: Not applicable



Analysis 5.3. Comparison 5 Infants with mild hip dysplasia on ultrasound: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone, Outcome 3 Any treatment.

Review: Screening programmes for developmental dysplasia of the hip in newborn infants

Comparison: 5 Infants with mild hip dysplasia on ultrasound: Treatment guided by ultrasound surveillance versus treatment based on clinical assessment alone

Outcome: 3 Any treatment

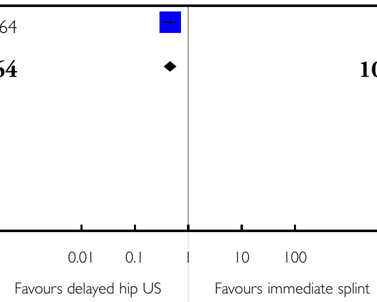
Study or subgroup	Delayed hip US n/N	Immediate splinting n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Rosendahl 2010	29/64	64/64		100.0 %	0.46 [0.35, 0.60]
Total (95% CI)	**64**	**64**		**100.0 %**	**0.46 [0.35, 0.60]**

Total events: 29 (Delayed hip US), 64 (Immediate splinting)

Heterogeneity: not applicable

Test for overall effect: Z = 5.73 (P < 0.00001)

Test for subgroup differences: Not applicable



APPENDICES

Appendix 1. MEDLINE search strategy

Seached through PubMed:

1. infant, newborn = 443316
2. “hip dislocation, congenital” = 6963
3. “mass screening” = 67567
4. #1 AND #2“ = 1893
5. #4 AND #3 = 162

Appendix 2. EMBASE search strategy

1. infant, newborn = 405323
2. ”hip dislocation, congenital“ = 4927
3. ”mass screening“ = 40956
4. ”hip dysplasia“ = 3784
5. #1 AND (#2 or #4) AND #4 = 18

Appendix 3. CENTRAL search strategy

1. ”infant, newborn“
2. ”hip dislocation, congenital“
3. ”screening“
4. #1 AND #2 AND #3 = 13 trials

HISTORY

Protocol first published: Issue 1, 2004

Review first published: Issue 9, 2011

CONTRIBUTIONS OF AUTHORS

DS and TH wrote the review based on an earlier protocol originally submitted by LM (Liz McKechnie).

LM contributed to protocol, but has not been an active author on the review preparation.

DO supervised the review.

DECLARATIONS OF INTEREST

None

SOURCES OF SUPPORT

Internal sources

- Australian Satellite of the Cochrane Neonatal Group, Australia.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

For infants with clinically unstable hips

- Clinical examination alone versus clinical examination with ultrasound to determine treatment

The following comparison was added as it was thought inappropriate to combine it with the comparison examining the effects in ’infants with clinically unstable hips’:

- For infants with mild hip dysplasia on ultrasound.

Secondary outcomes

- ’Any treatment’ (added).

- 'Delayed abduction splinting (after 8 weeks of age)' (added).

Documentation of criteria for 'Risk of bias' table. Documentation of quantification of heterogeneity using I^2 statistic; documentation of use of funnel plot to examine for publication or other bias; subgroup analyses of studies according to experience or training of clinical examiner and ultrasound (see methods).

INDEX TERMS

Medical Subject Headings (MeSH)

Delayed Diagnosis [*adverse effects]; Hip Dislocation, Congenital [*diagnosis; therapy; ultrasonography]; Infant, Newborn; Mass Screening [*methods]; Physical Examination [methods]; Program Evaluation; Remission, Spontaneous; Splints; Time Factors

MeSH check words

Humans; Infant