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Evaluating the role of pre-reduction hip traction in the management of infants and children with developmental dysplasia of the hip (DDH): protocol for a systematic review and planned meta-analysis.

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EVALUATING THE ROLE OF PRE-REDUCTION HIP TRACTION IN THE MANAGEMENT OF INFANTS AND CHILDREN WITH DEVELOPMENTAL DYSPLASIA OF THE HIP (DDH): PROTOCOL FOR A SYSTEMATIC REVIEW AND PLANNED META-ANALYSIS.

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In accordance with the guidelines, our systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 19 May 2017 and was last updated 30th June 2017 (registration number CRD42017064254) Walton S, Schaeffer E, Mulpuri K, Cundy P, Williams N. Evaluating the role of pre-reduction hip traction in the management of infants and children with developmental dysplasia of the hip (DDH): a systematic review and meta-analysis. PROSPERO: International prospective register of systematic reviews. 2017. CRD42017064254 https://www.crd.york.ac.uk/prospero/display_record.asp?ID=CRD42017064254.
In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

NW is the guarantor. NW and PC were involved in the conception of the project. SW, NW and ES drafted the manuscript. All authors contributed to the development of the selection criteria, the risk of bias assessment strategy and data extraction criteria. SW and ES developed the search strategy. ES provided methodological expertise. PC, NW and KM provided expertise on DDH. All authors read, provided feedback and approved the final manuscript.
The Centre for Orthopaedic and Trauma Research (The University of Adelaide) is the Sponsor of the review. No funding from the Centre for Orthopaedic and Trauma Research has been received for this review. The Centre for Orthopaedic and Trauma Research is not involved in any other aspect of the project's design.

Word Count 4,123

ABSTRACT

Introduction

Developmental dysplasia of the hip (DDH) affects 4 to 6 per 1000 live births in developed countries. Effective treatment to re-align the hip is necessary to avoid long-term morbidities and maximise functional outcome. Treatment options depend on patient age but typically involve hip bracing and/or reduction under general anaesthetic. Some centres also employ pre-reduction hip traction. Historical papers suggest traction reduces risk of avascular necrosis (AVN) femoral head and reduces requirement for open reduction. However, several studies including a large retrospective cohort study, dispute this. We propose to perform the first systematic review and meta-analysis to clarify the value of pre-reduction hip traction in the management of DDH in children under the age of three years by identifying whether it impacts on the rate of successful closed reduction (CR), risk of AVN, and whether it is associated with any complications.

Methods and analysis

We will search Medline, EMBASE and the Cochrane Central Register of Controlled Trials to identify potentially relevant studies. Studies reporting on incidence of successful CR, AVN femoral head and complications associated with pre-reduction hip traction in children of less than three years old with DDH will be eligible for inclusion. Only randomised controlled trials, prospective and retrospective case-control and comparative cohort studies will be included in quantitative review. There will be no study design restrictions for inclusion in qualitative review. Following study selection, full-text paper retrieval, data extraction and synthesis, studies will be assessed for risk of bias and heterogeneity. If the included studies are sufficiently homogenous then we will perform meta-analysis. A narrative synthesis of the systematic review's results will also be presented.

Ethics and dissemination

Formal ethical approval is not required as primary patient data will not be collected. The systematic review's results will be disseminated through a peer-reviewed publication.

Registration CRD42017064254

Strengths and limitations of this study

Strengths and limitations of study

- This is the first systematic review to investigate the impact of pre-reduction hip traction on clinical outcomes in DDH, and its results should help guide clinical management decisions or will be hypothesis generating for future prospective comparative studies.
- The proposed systematic review and meta-analysis will follow the Preferred Reporting Items for Systematic Reviews and Meta Analyses (PRISMA) guidelines, ensuring uniform structure and reporting within the review.
- Two reviewers will screen for study eligibility and perform the risk of bias assessment, minimising the chance of reviewer-based bias in the systematic review.
- A limitation of the study is that we will only include articles reported in the English language.

INTRODUCTION

Background

The term 'developmental dysplasia of the hip' (DDH) encompasses a range of conditions in which the femoral head and acetabulum are misaligned, grow abnormally, or both, leading to hip joint instability. Developed countries report an incidence of around 4-6 cases of DDH per 1000 live births although this depends on the definition used for DDH and the population studied.[1,2] DDH is usually detected within the first months of life through screening programmes consisting of physical examination and either universal or selective medical imaging.[3] Hips that are positive for Barlow's sign (dislocatable/subluxable) and/or Ortolani's sign (dislocated and reducible), dislocated and irreducible, or unstable on ultrasound examination should be monitored or treated. The aim of treatment is to re-align the hip joint in order to avoid associated long-term morbidities including muscle weakness, degenerative arthritis and chronic pain, and to maximise functional outcome.

Typically, treatment for DDH in a child less than six months old is with a Pavlik harness and/or a fixed abduction brace.[4] If the child is over six months old or if the aforementioned holding devices fail, then closed reduction (CR) under general anaesthesia followed by hip spica casting is generally attempted.[4] Some surgeons/centres employ hip traction prior to CR, but there is currently no consensus on whether this pre-reduction hip traction is beneficial.

Historical papers suggested pre-reduction traction was associated with lower rates of avascular necrosis (AVN) of the femoral head and reduced requirement for open reduction (OR).[5-8] However, several studies including a large retrospective cohort study, dispute this.[9-12]

Further investigation is warranted to clarify the value of pre-reduction traction in the management of DDH in infants and children. By identifying whether pre-reduction traction impacts on the rate of successful CR and risk of AVN, and by analysing these outcomes in different patient ages and following different traction methods, this review should help guide clinicians in making patient-specific management decisions.

Objectives

The aim of this systematic review is to evaluate if there is a role for pre-reduction hip traction in the management of infants and children with DDH. To this end, the proposed systematic review will answer the following questions:

1) How does pre-reduction hip traction impact on the likelihood of successful CR in infants and children with DDH compared to no pre-reduction traction?

2) How does pre-reduction hip traction impact on the risk of AVN of the femoral head and/or neck in infants and children with DDH compared to no pre-reduction traction?

3) What are the other adverse events/complications arising from pre-reduction traction and what is their incidence?

4) Does the rate of successful CR and the risk of AVN following pre-reduction traction in infants and children with DDH vary depending on the age of the infant or child and the severity of DDH?

5) Does the rate of successful CR and the risk of AVN following pre-reduction traction in infants and children with DDH vary depending on type of traction used, whether it is performed on an inpatient or outpatient basis, and/or on its duration?

6) What is the financial impact of pre-reduction traction on the healthcare provider, the patient's family, and on society in terms of the patient's parents/carers being absent from work?

METHODS

Eligibility Criteria

Studies will be selected according to the eligibility criteria below.

Study designs and report characteristics

Only randomised controlled trials, prospective and retrospective case-control studies, and prospective and retrospective comparative cohort studies will be included in quantitative review/meta-analysis. There will be no restrictions set on the study designs eligible for inclusion in qualitative review. No geographical, publication date or publication status restrictions shall be imposed.

Participants

We will include studies on patients diagnosed with any degree of DDH (as diagnosed using any recognised diagnostic criteria) and starting treatment at less than three years of age. We will include studies that additionally study children over three years of age if the data for outcomes in those under three years of age is presented separately. Due to possible discrepancies in DDH definition usage, we will extract DDH definition used in individual studies where available. We will exclude studies including patients with diagnosed neuromuscular disorders unless the patients with neuromuscular disorders are reported separately to patients without neuromuscular disorders. We will also exclude studies only including patients who started treatment for DDH at over three years of age.

Intervention

We will include studies on pre-reduction hip traction using skin traction. We will include studies on overhead (Bryant's) traction and on longitudinal traction and studies that assess both. Studies of inpatient and outpatient traction will be included. We will consider including studies assessing other types of pre-reduction traction on a

case-by-case basis. No inclusion limits will be set on pre-reduction traction duration or weights used in the studies. The rest of the treatment received within the studies should ideally be in keeping with standard care at the time of the study. For example, preliminary hip bracing with Pavlik harness or fixed abduction brace would be expected to have been attempted in a patient of less than six months of age at diagnosis and a hip spica cast (or accepted alternative) should be applied post-reduction. We will exclude studies where the intervention is skeletal rather than skin traction and where traction is being used as intended definitive treatment. We will exclude studies in which non-standard or experimental treatment is being trialled in other areas of DDH management. We will exclude studies where open reduction is performed routinely following traction.

Comparators

We will include studies comparing patients fulfilling the participant and intervention inclusion criteria above with those fulfilling the participant inclusion criteria but who were not treated with pre-reduction hip traction. The rest of the treatment received by the comparator group should ideally be in line with standard care at the time the study was carried out. We will collect information on whether adductor tenotomy and/or psoas tenotomy was performed at the time of CR. We will also include studies comparing outcomes for overhead (Bryant's) traction with those for longitudinal traction. We will include studies comparing outcomes for different traction duration and patient age subgroups.

Outcomes

Studies reporting on the following primary outcomes will be eligible for inclusion:

- Incidence of successful CR - defined as a hip that was reduced into the acetabulum at the time of the attempted closed reduction, remained reduced and did not require repeat closed reduction or open reduction
- Incidence of AVN of the femoral head and/or neck (as defined by any recognised diagnostic methods e.g. Salter criteria) post-reduction. Degree of AVN (as defined by any recognised classification method e.g. Bulcholz/Ogden classification)
- Occurrence of adverse events/complications arising from pre-reduction hip traction and their incidence

If the above outcomes are reported, they will be analysed and graded. If the above outcomes are not reported then we will analyse and grade surrogate outcomes described below. Therefore, studies reporting on the following secondary outcomes will be eligible for inclusion:

- Incidence of cases going directly to open reduction
- Incidence of residual subluxation post-operatively
- Incidence of secondary procedures, for example, Pelvic and femoral osteotomies
- Incidence of acetabular dysplasia
- Long-term radiological outcome of treatment, for example, Thomas grade
- Long-term clinical outcome of treatment based on physical examination findings and reporting of symptoms

Studies assessing patient and clinician acceptability and the financial implications of pre-reduction traction on the healthcare provider, the patient's family, and society will also be included where available. These outcomes will be described in a qualitative section of the paper rather than in the main quantitative review and meta-analysis.

Outcomes will be collected as they are reported in each study. Due to possible discrepancies in outcome definitions used, we will extract definitions used in each of the studies included. We will extract outcomes in all data forms (for example, dichotomous, continuous) as they are reported within the study.

Timing

Studies will be selected for inclusion based on the length of follow-up of outcomes. The following will be used as a guide for all study designs:

- For studies examining successful CR as an endpoint, follow-up should be at least six months. This should help ensure follow-up encompasses hip spica cast removal and likely will capture if further operative procedures are indicated in order to achieve reduction of the hip.
- For studies examining AVN as an endpoint, follow-up should be at least two years. AVN secondary to reduction cannot be assessed for at least six months post-reduction and can become apparent up to two years post-reduction.

Assessment of residual subluxation may be made with first hip spica cast change at six weeks post-reduction. The assessment process will be ongoing over the three to six months post-reduction. We note that acetabular dysplasia tends to be assessed in mid-childhood and long-term outcomes should ideally include more than 20 years of radiological and functional data. However, this follow-up timeframe is not included in the majority of studies.

Setting
There will be no restrictions on the type of setting.

Language
We will include articles reported in the English language. A list of possibly relevant titles in other languages will be provided as an appendix.

Search Strategy
Literature search strategies will be developed using medical subject headings (MeSH) and text words related to developmental dysplasia of the hip and hip traction. We will search the following electronic bibliographic databases: MEDLINE (OVID interface, 1948 onwards), Embase (OVID interface, 1980 onwards), and the Cochrane Central Register of Controlled Trials (Wiley interface, current issue). The electronic database search will be supplemented by searching for trial protocols through metaRegister (http://www.controlled-trials.com/mrct/). To ensure literature saturation, we will scan the reference lists of included studies or relevant reviews identified through the search. We will circulate a bibliography of the included articles to the systematic review team, as well as to DDH experts identified by the team. Searches will be re-run just before the final analysis and further studies retrieved for inclusion. We will include articles reported in the English language. A list of possibly relevant titles in other languages will be provided as an appendix. There will be no date restrictions.

Only studies in humans will be sought. No other study design, date or language limitations will be imposed on the search, although only studies originally written in English or that have been translated into English will be included due to resource limitations. MEDLINE, Embase, and the Cochrane Central Register of Controlled Trials will be searched. The specific search strategies will be created by a Health Sciences Librarian with expertise in systematic review searching. The MEDLINE strategy will be developed with input from members of the systematic review team. If possible, the search strategy will be peer-reviewed by a second Health Sciences Librarian. The draft MEDLINE search strategies for each search question are shown below. After the MEDLINE strategy is finished, it will be modified to the syntax and subject headings of the other two databases. The International Clinical Trials Registry Platform (ICTRP) Search Portal and ClinicalTrials.gov will be searched for current and recent trials, and PROSPERO will be searched for current or recently completed systematic reviews.

Study Records
Data management: Systematic review data management software will not be used due to resource limitations. However, literature search results will be uploaded to EndNote, a citation manager, to facilitate sharing of references between reviewers and to help identify and remove duplicate references. In addition to this, in order to identify multiple publications on the same study and thus avoid double counting, we will compare author names, study location, sample size, pre-reduction traction characteristics and outcomes reported. Where multiple publications of the same study are found, we will compare the reports, looking for inconsistencies that might indicate study limitations. The systematic review team will develop screening and data extraction questionnaires based on inclusion and exclusion criteria and the Cochrane Consumers and Communication Review Group's data extraction template respectively. Both questionnaires will be incorporated into a Google form. The data inputted on each Google form will be automatically transferred onto a spreadsheet summary of the results to be shared amongst all reviewers.

Data selection: Two reviewers (SW and NW) will independently screen titles and abstracts yielded by the electronic search against the set inclusion and exclusion criteria. Studies that appear to be relevant will be read in full by both reviewers and a conclusion made as to whether the article should be included in the systematic review. The screening questionnaire section of the aforementioned Google form will be completed during this process, serving as a record of screened study characteristics and documenting rationale for excluding studies. Where there is discrepancy in conclusions made by the two reviewers, and this cannot be resolved through discussion, a senior reviewer (PC or KM) will be consulted for their opinion. None of the reviewers will be blinded to the study authors or institution. A PRISMA flow diagram will be created to illustrate the winnowing process.

Data collection: We will develop a data extraction questionnaire based on the Cochrane Consumers and Communication Review Group's data extraction template. We will create an instruction manual with decision rules to be used alongside the questionnaire. Two reviewers (SW and NW) will independently pilot the data extraction questionnaire on five randomly selected studies that have met screening criteria. Following this, they will discuss any necessary changes and tailor the form accordingly. Using the pre-piloted form, data extraction will be performed on all included studies by one reviewer (SW). A random subset of data extracted will be verified by another reviewer (NW) for quality control purposes. We will contact trial authors via email where clarification or additional information is required during the data extraction process.

Data Items

The following data will be extracted from included studies:

General information on study: title, author, publication status, year of publication, year study was conducted, author contact details, funding source and any conflicts of interest, original language.

Study methods: stated aim of study, study design, number of groups in the study, consumer involvement in the study (for example, in delivering patient care and in evaluating hip traction and its outcomes).

Study participants: description (i.e. infants with DDH, their parents/carers, healthcare professionals), age range and mean age of participants, at what point age is taken (i.e. at DDH diagnosis, at commencement of treatment, or at attempted closed reduction), gender, geographic location of participants (including city, state and country), study setting (i.e. inpatient or outpatient), methods of recruitment for study, inclusion and exclusion criteria for participation in study, any stated excluded groups and rationale for exclusion. If available, the following data will also be collected: severity of DDH at diagnosis, diagnostic methods, DDH definition and classification criteria used, previous treatment received (i.e. Pavlik Harness, fixed abduction brace), laterality of DDH.

Study numbers: number of patients identified as eligible for study inclusion, number of patients excluded, number of patients refusing participation in study (prospective studies only), number of patients in traction group, number of patients in control group, number of patients not completing treatment, number of patients lost to follow-up, number of patients included in the analysis for each outcome (see Item 13a for list of outcomes to be collected) and for each group; intervention and control.

Intervention characteristics: type of pre-reduction traction used (i.e. overhead or longitudinal), duration of traction, weights used for traction, location of traction (i.e. inpatient or outpatient), further details of location (i.e. type of hospital, type of ward), who performed the traction and what training was given, description of how traction was performed including materials used and observations and monitoring performed during traction, any tailoring of traction during treatment and, if so, based on what decision rules, details of any guidelines or information used to guide treatment in the study, details of assessment of compliance with intervention. Data on whether adductor/psoas tenotomy was performed at CR and for how long a hip spica cast was applied post-operatively should also be collected in this section. For the control group: description of treatment received. For both the intervention and the control groups, we will attempt to collect data on age range and mean age of participants at commencement of the intervention in this section.

Outcomes and Prioritisation

Data will be collected on the following primary outcomes:

- Incidence of successful CR - defined as a hip that was reduced into the acetabulum at the time of the attempted closed reduction, remained reduced and did not require repeat closed reduction or open reduction
- Incidence of AVN of the femoral head and/or neck (as defined by any recognised diagnostic methods, for example, Salter criteria) post-reduction. Degree of AVN (as defined by any recognised classification method, for example, Bulcholz/Ogden classification)
- Occurrence of other adverse events arising from pre-reduction hip traction and their incidence

The definition of successful CR and the criteria used for AVN diagnosis and classification of its severity will be collected. The methods used for assessing successful CR and AVN will be collected as will the timing of the assessments for these two outcomes, including the frequency and duration of assessments and follow-up. A note on direction of effect will be made in this section alongside data collected on the outcomes to help guard against errors

when the data from different studies is collated on a particular outcome. Data on adverse events relating to pre-reduction traction including complications (for example, pressure sores), side effects (for example, pain), complaints, and high levels of patient/parent dissatisfaction will be collected. The method of assessing for these adverse events (for example, through parental questionnaires, childhood pain scales) and the frequency and duration of monitoring for these adverse events will be collected. If adverse events are not reported by an included study, we will record whether adverse events were or were not investigated by the study. We intend to refine our outcome definitions during the systematic review process based on outcomes reported in the included studies.

Data will be collected on the following secondary outcomes:

- Incidence of cases going directly to open reduction
- Incidence of residual subluxation post-operatively
- Incidence of secondary procedures, for example, pelvic and femoral osteotomies
- Incidence of acetabular dysplasia
- Long-term radiological outcome of treatment, for example, Thomas grade
- Long-term clinical outcome of treatment based on physical examination findings and reporting of symptoms
- Acceptability of pre-reduction hip traction to patient, parent/carer and healthcare provider
- Financial implications of pre-reduction traction on the healthcare provider, the patient's family, and society

For those cases going directly to open reduction, the rationale for this should be recorded. How residual subluxation, acetabular dysplasia, radiological and clinical outcome were defined and graded in each study and how they were assessed for including frequency of assessments and duration of follow-up will be collected. Type of secondary procedure will be recorded by intervention name and incidence of each secondary procedure will be collected. We will also collect information on how patients who did not attend for planned reviews were followed-up by the studies. Long-term clinical outcome is a composite of physical examination findings and patient or parent/carer reported symptoms and we intend to analyse these two components separately.

Risk of bias individual studies

We anticipate that our review will encompass a variety of study designs including randomised control trials, case-control and comparative cohort studies. Choice of risk of bias tool will depend on the study design.

For randomised controlled trials, we will use The Cochrane Collaboration's tool for assessing risk of bias. This tool includes seven domains to consider; random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias. We will use the Cochrane Handbook criteria to guide decision making. Each domain will be marked as either 'high risk', 'unclear' or 'low risk.' It will not have been possible to conceal allocation or blind participants or personnel in studies of pre-reduction hip traction as it is an intervention that will be obviously visible to all involved in the patient's care. Thus, we anticipate studies of pre-reduction hip traction to automatically score as 'high risk' in these domains. Where a judgement cannot be made based on the information provided by the original paper, a judgement of 'unclear' will be made and the study authors will be contacted for further information.

For case-control and comparative cohort studies we will use the Newcastle-Ottowa quality assessment scale for case-control and cohort studies respectively. This generic scale will be tailored to meet our review's requirements. Studies will be assessed on the domains of selection of study groups, comparability of groups and on ascertainment of the outcome of interest. We will consider each item on the scale separately rather than assigning an overall score. The Newcastle-Ottowa Scale manual will be used in conjunction with these scales. For each assessment completed, descriptions of the study's methods relating to each point will be included to justify decisions made. Risk of bias assessment will be performed by SW (review lead) and NW (content expert) in duplicate and disagreements on scoring of individual studies will be resolved by discussion with a third reviewer, ES (methodological expert). Blinding of the reviewers to the study authors and institutions will not be performed.

Data Synthesis

To proceed to meta-analysis, we will need to assess homogeneity of the included studies. We will particularly examine whether the patient characteristics (for example, age and degree of DDH) and the way in which traction was applied (for example, type of traction, traction duration and weights used) are sufficiently similar between included studies. We anticipate that outcomes of included studies should be similar given our relatively strict

inclusion criteria for this aspect of study design. If the included studies are adequately homogenous then a meta-analysis will be performed.

We will use risk ratio (RR) with 95% confidence interval as a measure of treatment effect of pre-reduction hip traction on risk of successful CR and risk of AVN.

We will deal with missing outcome data in published reports by contacting study authors and requesting the relevant data. Where the data is not available, we will consider using imputation methods and undertaking sensitivity analyses to assess the potential impact of missing data on the cumulative estimate.

Clinical heterogeneity of included studies will be assessed by examining patient and intervention characteristics. Statistical heterogeneity will be assessed. If high levels exist, we will attempt to account for this by subgroup analysis.

We will use statistical software alongside guidance from the Cochrane Handbook for Systematic Reviews of Interventions to combine the outcomes from the studies. Method used for meta-analysis will depend on the results of the tests of statistical heterogeneity. A fixed effects model will be used if the tests are not significant and a random effects model will be used if there is significant statistical heterogeneity. If there is considerable statistical heterogeneity between studies, then a meta-analysis will not be performed and a solely qualitative summary will be presented.

Subgroup analysis will be used to help answer our systematic review questions 4 and 5 and investigate possible sources of heterogeneity between studies. We will compare outcomes of pre-reduction traction in patients of different age groups (i.e. <3months versus >3months) and with different degrees of DDH (i.e. reducible versus irreducible dislocated hips). We will compare outcomes for overhead versus longitudinal traction, inpatient versus outpatient traction and compare outcomes for different traction durations and weights used.

A narrative synthesis of the systematic review's results will be presented in addition to any meta-analysis performed. In this narrative synthesis, we will describe the results from each study, focusing on each of the systematic review's questions in turn. The characteristics of each study will be tabulated alongside the text to allow easier comparison of patient, intervention and outcome characteristics. The results from all studies will be described including those deemed at 'high-risk' of bias, in anticipation of the majority of included studies automatically scoring as 'high-risk' on the 'blinding of participants and personnel' domain. Studies scoring as 'high-risk' in other domains will be highlighted as such in their description. Some studies, for example, case reports, will only feature in the section answering systematic review question 3. We also intend to do a cost of treatment analysis to answer systematic review question 6.

Meta-bias(es)

To assess for selective reporting of outcomes, we will search for the study's protocol on the Clinical Trial Register at the International Clinical Trials Registry Platform of the World Health Organisation and compare intended outcomes on the protocol versus reported outcomes.

Confidence in Cumulative Estimate

The strength of evidence for our review's estimate of RR of successful CR and RR of AVN will be assessed using the systematic Grading of Recommendations, Assessment, Development and Evaluations (GRADE) approach. A score for quality of our evidence; high, moderate, low or very low will be allocated for both cumulative estimates.

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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item and page number where item can be found
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review: page 1 (title page)
Update	1b	If the protocol is for an update of a previous systematic review, identify as such: N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number: page 1
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author: page 1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review: page 1
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments: N/A
Support:		
Sources	5a	Indicate sources of financial or other support for the review: page 1
Sponsor	5b	Provide name for the review funder and/or sponsor: page 1
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol: page 1
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known: page 2
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO): page 3
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review: page 3
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage: page 5
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated: page 5
Study records:		

Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review: page 5
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis): page 5
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators: page 6
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications: page 6
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale: page 6
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis: page 7
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised: page 7
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ): page 8
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression): page 8
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned: page 8
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
: page 8		
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE): page 8

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

BMJ Open

Evaluating the role of pre-reduction hip traction in the management of infants and children with developmental dysplasia of the hip (DDH): protocol for a systematic review and planned meta-analysis.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-019599.R1
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Date Submitted by the Author:	16-Nov-2017
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Primary Subject Heading:	Surgery
Secondary Subject Heading:	Paediatrics
Keywords:	Paediatric orthopaedics < ORTHOPAEDIC & TRAUMA SURGERY, developmental dysplasia of the hip (DDH), preoperative traction, avascular necrosis (AVN), closed reduction, systematic review

EVALUATING THE ROLE OF PRE-REDUCTION HIP TRACTION IN THE MANAGEMENT OF INFANTS AND CHILDREN WITH DEVELOPMENTAL DYSPLASIA OF THE HIP (DDH): PROTOCOL FOR A SYSTEMATIC REVIEW AND PLANNED META-ANALYSIS.

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In accordance with the guidelines, our systematic review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 19 May 2017 and was last updated 30th June 2017 (registration number CRD42017064254) Walton S, Schaeffer E, Mulpuri K, Cundy P, Williams N. Evaluating the role of pre-reduction hip traction in the management of infants and children with developmental dysplasia of the hip (DDH): a systematic review and meta-analysis. PROSPERO: International prospective register of systematic reviews. 2017. CRD42017064254 https://www.crd.york.ac.uk/prospero/display_record.asp?ID=CRD42017064254.
In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

NW is the guarantor. NW and PC were involved in the conception of the project. SW, NW and ES drafted the manuscript. All authors contributed to the development of the selection criteria, the risk of bias assessment strategy and data extraction criteria. SW and ES developed the search strategy. ES provided methodological expertise. PC, NW and KM provided expertise on DDH. All authors read, provided feedback and approved the final manuscript. The Centre for Orthopaedic and Trauma Research (The University of Adelaide) is the Sponsor of the review. No funding from the Centre for Orthopaedic and Trauma Research has been received for this review. The Centre for Orthopaedic and Trauma Research is not involved in any other aspect of the project's design.

Word Count 4,081

ABSTRACT

Introduction

Developmental dysplasia of the hip (DDH) affects 4 to 6 per 1000 live births in developed countries. Effective treatment to re-align the hip is necessary to avoid long-term morbidities and maximise functional outcome. Treatment options depend on patient age but typically involve hip bracing and/or reduction under general anaesthetic. Some centres also employ pre-reduction hip traction. Historical papers suggest traction reduces risk of avascular necrosis (AVN) femoral head and reduces requirement for open reduction. However, several studies including a large retrospective cohort study, dispute this. We propose to perform the first systematic review and meta-analysis to clarify the value of pre-reduction hip traction in the management of DDH in children under the age of three years by identifying whether it impacts on the rate of successful closed reduction (CR) and risk of AVN.

Methods and analysis

We will search Medline, EMBASE and the Cochrane Central Register of Controlled Trials to identify potentially relevant studies. Studies reporting on incidence of successful CR, AVN femoral head and complications associated with pre-reduction hip traction in children of less than three years old with DDH will be eligible for inclusion. Only randomised controlled trials, prospective and retrospective case-control and comparative cohort studies will be included in quantitative review. There will be no study design restrictions for inclusion in qualitative review. Following study selection, full-text paper retrieval, data extraction and synthesis, studies will be assessed for risk of bias and heterogeneity. If the included studies are sufficiently homogenous then we will perform meta-analysis. A narrative synthesis of the systematic review's results will also be presented.

Ethics and dissemination

Formal ethical approval is not required as primary patient data will not be collected. The systematic review's results will be disseminated through a peer-reviewed publication.

Competing Interests

None declared

Registration CRD42017064254

Strengths and limitations of this study

Strengths and limitations of study

- This is the first systematic review to investigate the impact of pre-reduction hip traction on clinical outcomes in DDH, and its results should help guide clinical management decisions or will be hypothesis generating for future prospective comparative studies.
- The proposed systematic review and meta-analysis will follow the Preferred Reporting Items for Systematic Reviews and Meta Analyses (PRISMA) guidelines, ensuring uniform structure and reporting within the review.
- Two reviewers will screen for study eligibility and perform the risk of bias assessment, minimising the chance of reviewer-based bias in the systematic review.
- A limitation of the study is that we will only include articles reported in the English language.

INTRODUCTION

Background

The term 'developmental dysplasia of the hip' (DDH) encompasses a range of conditions in which the femoral head and acetabulum are misaligned, grow abnormally, or both, leading to hip joint instability. Developed countries report an incidence of around 4-6 cases of DDH per 1000 live births although this depends on the definition used for DDH and the population studied.[1,2] DDH is usually detected within the first months of life through screening programmes consisting of physical examination and either universal or selective medical imaging.[3] Hips that are positive for Barlow's sign (dislocatable/subluxable) and/or Ortolani's sign (dislocated and reducible), dislocated and irreducible, or unstable on ultrasound examination should be monitored or treated. The aim of treatment is to re-align the hip joint in order to avoid associated long-term morbidities including muscle weakness, degenerative arthritis and chronic pain, and to maximise functional outcome.

Typically, treatment for DDH in a child less than six months old is with a Pavlik harness and/or a fixed abduction brace.[4] If the child is over six months old or if the aforementioned holding devices fail, then closed reduction (CR)

under general anaesthesia followed by hip spica casting is generally attempted.[4] Some surgeons/centres employ hip traction prior to CR, but there is currently no consensus on whether this pre-reduction hip traction is beneficial. Historical papers suggested pre-reduction traction was associated with lower rates of avascular necrosis (AVN) of the femoral head and reduced requirement for open reduction (OR).[5-8] However, several studies including a large retrospective cohort study, dispute this.[9-12]

Further investigation is warranted to clarify the value of pre-reduction traction in the management of DDH in infants and children. By identifying whether pre-reduction traction impacts on the rate of successful CR and risk of AVN, and by analysing these outcomes in different patient ages and following different traction methods, this review should help guide clinicians in making patient-specific management decisions.

Objectives

The primary aim of this systematic review is to evaluate how pre-reduction hip traction impacts on the likelihood of successful CR in infants and children with DDH compared to no pre-reduction traction.

Our secondary objectives are to evaluate how pre-reduction hip traction impacts on the risk of AVN of the femoral head and/or neck in infants and children with DDH compared to no pre-reduction traction, and to evaluate the incidence of other adverse events/complications arising from pre-reduction traction

METHODS

Eligibility Criteria

Studies will be selected according to the eligibility criteria below.

Study designs and report characteristics

Only randomised controlled trials, prospective and retrospective case-control studies, and prospective and retrospective comparative cohort studies will be included in quantitative review/meta-analysis. There will be no restrictions set on the study designs eligible for inclusion in qualitative review. No geographical, publication date or publication status restrictions shall be imposed.

Participants

We will include studies on patients diagnosed with any degree of DDH (as diagnosed using any recognised diagnostic criteria) and starting treatment at less than three years of age. We will include studies that additionally study children over three years of age if the data for outcomes in those under three years of age is presented separately. Due to possible discrepancies in DDH definition usage, we will extract DDH definition used in individual studies where available. We will exclude studies including patients with diagnosed neuromuscular disorders unless the patients with neuromuscular disorders are reported separately to patients without neuromuscular disorders. We will also exclude studies only including patients who started treatment for DDH at over three years of age.

Intervention

We will include studies on pre-reduction hip traction using skin traction. We will include studies on overhead (Bryant's) traction and on longitudinal traction and studies that assess both. Studies of inpatient and outpatient traction will be included. We will consider including studies assessing other types of pre-reduction traction on a case-by-case basis. No inclusion limits will be set on pre-reduction traction duration or weights used in the studies. The rest of the treatment received within the studies should ideally be in keeping with standard care at the time of the study. For example, preliminary hip bracing with Pavlik harness or fixed abduction brace would be expected to have been attempted in a patient of less than six months of age at diagnosis and a hip spica cast (or accepted alternative) should be applied post-reduction. We will exclude studies where the intervention is skeletal rather than skin traction and where traction is being used as intended definitive treatment. We will exclude studies in which non-standard or experimental treatment is being trialled in other areas of DDH management. We will exclude studies where open reduction is performed routinely following traction.

Comparators

We will include studies comparing patients fulfilling the participant and intervention inclusion criteria above with those fulfilling the participant inclusion criteria but who were not treated with pre-reduction hip traction. The rest of the treatment received by the comparator group should ideally be in line with standard care at the time the study was

carried out. We will collect information on whether adductor tenotomy and/or psoas tenotomy was performed at the time of CR. We will also include studies comparing outcomes for overhead (Bryant's) traction with those for longitudinal traction. We will include studies comparing outcomes for different traction duration and patient age subgroups.

Outcomes

Studies reporting on the following outcomes will be eligible for inclusion:

Primary Outcome:

- Incidence of successful CR - defined as a hip that was reduced into the acetabulum at the time of the attempted closed reduction, remained reduced and did not require repeat closed reduction or open reduction

Secondary Outcomes:

- Incidence of AVN of the femoral head and/or neck (as defined by any recognised diagnostic methods, for example, Salter criteria) post-reduction. Degree of AVN (as defined by any recognised classification method, for example, Bulcholz/Ogden classification)
- Incidence of other adverse events/complications arising from pre-reduction traction

If the above outcomes are reported, they will be analysed and graded. If the above outcomes are not reported then we will analyse surrogate outcomes described below. Therefore, studies reporting on the following outcomes will also be eligible for inclusion:

- Incidence of cases going directly to open reduction
- Incidence of residual subluxation post-operatively
- Incidence of secondary procedures, for example, pelvic and femoral osteotomies
- Incidence of acetabular dysplasia

Outcomes will be collected as they are reported in each study. Due to possible discrepancies in outcome definitions used, we will extract definitions used in each of the studies included. We will extract outcomes in all data forms (for example, dichotomous, continuous) as they are reported within the study.

Timing

Studies will be selected for inclusion based on the length of follow-up of outcomes. The following will be used as a guide for all study designs:

- For studies examining successful CR as an endpoint, follow-up should be at least six months. This should help ensure follow-up encompasses hip spica cast removal and likely will capture if further operative procedures are indicated in order to achieve reduction of the hip.
- For studies examining AVN as an endpoint, follow-up should be at least two years. AVN secondary to reduction cannot be assessed for at least six months post-reduction and can become apparent up to two years post-reduction.

Assessment of residual subluxation may be made with first hip spica cast change at six weeks post-reduction. The assessment process will be ongoing over the three to six months post-reduction. We note that acetabular dysplasia tends to be assessed in mid-childhood and long-term outcomes should ideally include more than 20 years of radiological and functional data. However, this follow-up timeframe is not included in the majority of studies.

Setting

There will be no restrictions on the type of setting.

Language

We will include articles reported in the English language. A list of possibly relevant titles in other languages will be provided as an appendix.

Search Strategy

Literature search strategies will be developed using medical subject headings (MeSH) and text words related to developmental dysplasia of the hip and hip traction. We will search the following electronic bibliographic databases: MEDLINE (OVID interface, 1948 onwards), Embase (OVID interface, 1980 onwards), and the Cochrane Central Register of Controlled Trials (Wiley interface, current issue). The electronic database search will be supplemented

by searching for trial protocols through metaRegister (http://www.controlled-trials.com/mrct/). To ensure literature saturation, we will scan the reference lists of included studies or relevant reviews identified through the search. We will circulate a bibliography of the included articles to the systematic review team, as well as to DDH experts identified by the team. Searches will be re-run just before the final analysis and further studies retrieved for inclusion. We will include articles reported in the English language. A list of possibly relevant titles in other languages will be provided as an appendix. There will be no date restrictions.

Only studies in humans will be sought. No other study design, date or language limitations will be imposed on the search, although only studies originally written in English or that have been translated into English will be included due to resource limitations. MEDLINE, Embase, and the Cochrane Central Register of Controlled Trials will be searched. The specific search strategies will be created by a Health Sciences Librarian with expertise in systematic review searching. The MEDLINE strategy will be developed with input from members of the systematic review team. If possible, the search strategy will be peer-reviewed by a second Health Sciences Librarian. The draft MEDLINE search strategies for each search question are shown below. After the MEDLINE strategy is finished, it will be modified to the syntax and subject headings of the other two databases. The International Clinical Trials Registry Platform (ICTRP) Search Portal and ClinicalTrials.gov will be searched for current and recent trials, and PROSPERO will be searched for current or recently completed systematic reviews.

Study Records

Data management: Systematic review data management software will not be used due to resource limitations. However, literature search results will be uploaded to EndNote, a citation manager, to facilitate sharing of references between reviewers and to help identify and remove duplicate references. In addition to this, in order to identify multiple publications on the same study and thus avoid double counting, we will compare author names, study location, sample size, pre-reduction traction characteristics and outcomes reported. Where multiple publications of the same study are found, we will compare the reports, looking for inconsistencies that might indicate study limitations. The systematic review team will develop screening and data extraction questionnaires based on inclusion and exclusion criteria and the Cochrane Consumers and Communication Review Group's data extraction template respectively. Both questionnaires will be incorporated into a Google form. The data inputted on each Google form will be automatically transferred onto a spreadsheet summary of the results to be shared amongst all reviewers.

Data selection: Two reviewers (SW and NW) will independently screen titles and abstracts yielded by the electronic search against the set inclusion and exclusion criteria. Studies that appear to be relevant will be read in full by both reviewers and a conclusion made as to whether the article should be included in the systematic review. The screening questionnaire section of the aforementioned Google form will be completed during this process, serving as a record of screened study characteristics and documenting rationale for excluding studies. Where there is discrepancy in conclusions made by the two reviewers, and this cannot be resolved through discussion, a senior reviewer (PC or KM) will be consulted for their opinion. None of the reviewers will be blinded to the study authors or institution. A PRISMA flow diagram will be created to illustrate the winnowing process.

Data collection: We will develop a data extraction questionnaire based on the Cochrane Consumers and Communication Review Group's data extraction template. We will create an instruction manual with decision rules to be used alongside the questionnaire. Two reviewers (SW and NW) will independently pilot the data extraction questionnaire on five randomly selected studies that have met screening criteria. Following this, they will discuss any necessary changes and tailor the form accordingly. Using the pre-piloted form, data extraction will be performed on all included studies by one reviewer (SW). A random subset of data extracted will be verified by another reviewer (NW) for quality control purposes. We will contact trial authors via email where clarification or additional information is required during the data extraction process.

Data Items

The following data will be extracted from included studies:

General information on study: title, author, publication status, year of publication, year study was conducted, author contact details, funding source and any conflicts of interest, original language.

Study methods: stated aim of study, study design, number of groups in the study, consumer involvement in the study

(for example, in delivering patient care and in evaluating hip traction and its outcomes).

Study participants: description (i.e. infants with DDH, their parents/carers, healthcare professionals), age range and mean age of participants, at what point age is taken (i.e. at DDH diagnosis, at commencement of treatment, or at attempted closed reduction), gender, geographic location of participants (including city, state and country), study setting (i.e. inpatient or outpatient), methods of recruitment for study, inclusion and exclusion criteria for participation in study, any stated excluded groups and rationale for exclusion. If available, the following data will also be collected: severity of DDH at diagnosis, diagnostic methods, DDH definition and classification criteria used, previous treatment received (i.e. Pavlik Harness, fixed abduction brace), laterality of DDH.

Study numbers: number of patients identified as eligible for study inclusion, number of patients excluded, number of patients refusing participation in study (prospective studies only), number of patients in traction group, number of patients in control group, number of patients not completing treatment, number of patients lost to follow-up, number of patients included in the analysis for each outcome (see Item 13a for list of outcomes to be collected) and for each group; intervention and control.

Intervention characteristics: type of pre-reduction traction used (i.e. overhead or longitudinal), duration of traction, weights used for traction, location of traction (i.e. inpatient or outpatient), further details of location (i.e. type of hospital, type of ward), who performed the traction and what training was given, description of how traction was performed including materials used and observations and monitoring performed during traction, any tailoring of traction during treatment and, if so, based on what decision rules, details of any guidelines or information used to guide treatment in the study, details of assessment of compliance with intervention. Data on whether adductor/psoas tenotomy was performed at CR and for how long a hip spica cast was applied post-operatively should also be collected in this section. For the control group: description of treatment received. For both the intervention and the control groups, we will attempt to collect data on age range and mean age of participants at commencement of the intervention in this section.

Outcomes and Prioritisation

Data will be collected on the following outcomes:

- Incidence of successful CR - defined as a hip that was reduced into the acetabulum at the time of the attempted closed reduction, remained reduced and did not require repeat closed reduction or open reduction
- Incidence of AVN of the femoral head and/or neck (as defined by any recognised diagnostic methods, for example, Salter criteria) post-reduction. Degree of AVN (as defined by any recognised classification method, for example, Bulcholz/Ogden classification)
- Occurrence of other adverse events arising from pre-reduction hip traction and their incidence

The definition of successful CR and the criteria used for AVN diagnosis and classification of its severity will be collected. The methods used for assessing successful CR and AVN will be collected as will the timing of the assessments for these two outcomes, including the frequency and duration of assessments and follow-up. A note on direction of effect will be made in this section alongside data collected on the outcomes to help guard against errors when the data from different studies is collated on a particular outcome. We intend to refine our outcome definitions during the systematic review process based on outcomes reported in the included studies.

Data will be collected on the following secondary outcomes:

- Incidence of cases going directly to open reduction
- Incidence of residual subluxation post-operatively
- Incidence of secondary procedures, for example, pelvic and femoral osteotomies
- Incidence of acetabular dysplasia

For those cases going directly to open reduction, the rationale for this should be recorded. How residual subluxation and acetabular dysplasia were defined and graded in each study and how they were assessed for including frequency of assessments and duration of follow-up will be collected. Type of secondary procedure will be recorded by intervention name and incidence of each secondary procedure will be collected. We will also collect information on how patients who did not attend for planned reviews were followed-up by the studies.

Risk of bias individual studies

We anticipate that our review will encompass a variety of study designs including randomised control trials, case-control and comparative cohort studies. Choice of risk of bias tool will depend on the study design.

For randomised controlled trials, we will use The Cochrane Collaboration's tool for assessing risk of bias. This tool includes seven domains to consider; random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other sources of bias. We will use the Cochrane Handbook criteria to guide decision making. Each domain will be marked as either 'high risk', 'unclear' or 'low risk.' It will not have been possible to conceal allocation or blind participants or personnel in studies of pre-reduction hip traction as it is an intervention that will be obviously visible to all involved in the patient's care. Thus, we anticipate studies of pre-reduction hip traction to automatically score as 'high risk' in these domains. Where a judgement cannot be made based on the information provided by the original paper, a judgement of 'unclear' will be made and the study authors will be contacted for further information.

For case-control and comparative cohort studies we will use the Newcastle-Ottowa quality assessment scale for case-control and cohort studies respectively. This generic scale will be tailored to meet our review's requirements. Studies will be assessed on the domains of selection of study groups, comparability of groups and on ascertainment of the outcome of interest. We will consider each item on the scale separately rather than assigning an overall score. The Newcastle-Ottowa Scale manual will be used in conjunction with these scales. For each assessment completed, descriptions of the study's methods relating to each point will be included to justify decisions made. Risk of bias assessment will be performed by SW (review lead) and NW (content expert) in duplicate and disagreements on scoring of individual studies will be resolved by discussion with a third reviewer, ES (methodological expert). Blinding of the reviewers to the study authors and institutions will not be performed.

Data Synthesis

A narrative synthesis of the systematic review's results will be presented. In this narrative synthesis, we will describe the results from each study, focusing on each of the systematic review's objectives in turn. The characteristics of each study will be tabulated alongside the text to allow easier comparison of patient, intervention and outcome characteristics. The results from all studies will be described including those deemed at 'high-risk' of bias, in anticipation of the majority of included studies automatically scoring as 'high-risk' on the 'blinding of participants and personnel' domain. Studies scoring as 'high-risk' in other domains will be highlighted as such in their description. Some studies, for example, case reviews will only be described in the qualitative results section.

To proceed to meta-analysis, we will need to assess homogeneity of the included studies. We will particularly examine whether the patient characteristics (for example, age and degree of DDH), the way in which traction was applied (for example, type of traction, traction duration and weights used), and outcome measures collected are sufficiently similar between included studies. If the included studies are adequately homogenous then a meta-analysis will be performed. If the outcome measures recorded in the studies are heterogeneous, then a meta-analysis of all included studies will not be appropriate. Instead, we would but perform quantitative analysis on subsets of studies reporting on the same objective outcome.

We will use risk ratio (RR) with 95% confidence interval as a measure of treatment effect of pre-reduction hip traction on rate of successful CR and risk of AVN.

We will deal with missing outcome data in published reports by contacting study authors and requesting the relevant data. Where the data is not available, we will consider using imputation methods and undertaking sensitivity analyses to assess the potential impact of missing data on the cumulative estimate.

Clinical heterogeneity of included studies will be assessed by examining patient and intervention characteristics. Statistical heterogeneity will be assessed. If high levels exist, we will attempt to account for this by subgroup analysis.

We will use statistical software alongside guidance from the Cochrane Handbook for Systematic Reviews of Interventions to combine the outcomes from the studies. Method used for meta-analysis will depend on the results of the tests of statistical heterogeneity. A fixed effects model will be used if the tests are not significant and a random effects model will be used if there is significant statistical heterogeneity. If there is considerable statistical heterogeneity between studies, then a meta-analysis will not be performed and a solely qualitative summary will be

presented.

Meta-bias(es)
To assess for selective reporting of outcomes, we will search for the study's protocol on the Clinical Trial Register at the International Clinical Trials Registry Platform of the World Health Organisation and compare intended outcomes on the protocol versus reported outcomes.

Confidence in Cumulative Estimate
The strength of evidence for our review's estimate of RR of successful CR and RR of AVN will be assessed using the systematic Grading of Recommendations, Assessment, Development and Evaluations (GRADE) approach. A score for quality of our evidence; high, moderate, low or very low will be allocated for both cumulative estimates.

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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item and page number where item can be found
ADMINISTRATIVE INFORMATION		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review: page 1 (title page)
Update	1b	If the protocol is for an update of a previous systematic review, identify as such: N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number: page 1
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author: page 1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review: page 1
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments: N/A
Support:		
Sources	5a	Indicate sources of financial or other support for the review: page 1
Sponsor	5b	Provide name for the review funder and/or sponsor: page 1
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol: page 1
INTRODUCTION		
Rationale	6	Describe the rationale for the review in the context of what is already known: page 2
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO): page 3
METHODS		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review: page 3
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage: page 5
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated: page 5
Study records:		

Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review: page 5
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis): page 5
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators: page 6
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications: page 6
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale: page 6
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis: page 7
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised: page 7
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ): page 8
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression): page 8
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned: page 8
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
: page 8		
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE): page 8

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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