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## Arthroplasties for hip fracture in adults (Protocol)

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**[Intervention Protocol]**

# Arthroplasties for hip fracture in adults

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## ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To determine the relative effects (benefits and harms) of different designs, articulations, and fixation techniques of arthroplasties for treating hip fractures in adults.

This will include assessment of the relative effects (benefits and harms) of the following.

- THR versus HA
- Cemented versus uncemented arthroplasties
- Alternative articulation designs in THA
- Different designs of HA, e.g. bipolar versus unipolar

## BACKGROUND

### Description of the condition

#### Epidemiology

A hip fracture, or proximal femoral fracture, is a break in the upper region of the femur (thigh bone) between the subcapital region (the area just under the femoral head) and 5 cm below the lesser trochanter (a bony projection of the upper femur). The incidence of hip fractures increases with age, and are most common in the older adult population (Court-Brown 2017; Kanis 2001). Hip fractures in younger adults are usually associated with poor bone health (Karantana 2011; Rogmark 2018). A small proportion of fractures occurring in younger people are as a result of high-energy trauma, such as road traffic collisions and sports injuries. Most hip fractures are fragility fractures associated with osteoporosis, such fractures resulting from mechanical forces that would not ordinarily result in fracture. The World Health Organization (WHO) has defined fragility fracture as those sustained from injuries equivalent to a fall from a standing height or less (Kanis 2001). In the UK, the mean age of a person with hip fracture is 83 years and approximately two-thirds occur in women (NHFD 2017).

Hip fractures are a major healthcare problem at the individual and population level, and present a huge challenge and burden to patients, healthcare systems, and society. The increased proportion of older adults in the world population means that the absolute number of hip fractures is rising rapidly worldwide. For example, in 2016 there were 65,645 new presentations of hip fracture to 177 trauma units in England, Wales, and Northern Ireland (NHFD 2017). Based on mid-2016 population estimates for these regions, this equates to an incidence rate of 108 cases per 100,000 population (ONS 2018). By 2050, the annual worldwide incidence is estimated to be six million hip fractures (Cooper 2011; Johnell 2004). Incident hip fracture rates are higher in industrialised countries compared to low- or middle-income countries. The highest hip fracture rates are seen across northern Europe and the USA, and the lowest in Latin America and Africa (Dhanwal 2011). There is also a north-south gradient seen in European studies, and similarly more fractures are seen in the north of the USA than in the south (Dhanwal 2011). The factors responsible for this variation are thought to be population demographics (with more elderly populations in countries with higher incidence rates) and the influence of ethnicity, latitude, and environmental factors such as socioeconomic deprivation (Bardsley 2013; Cooper 2011; Dhanwal 2011; Kanis 2012).

#### Burden of disease

Hip fractures are also associated with a high risk of death. For example, in England, Wales, and Northern Ireland, the 30-day mortality rate in 2016 remained high at 6.7%, despite a decline from 8.5% in 2011 and 7.1% in 2015 (NHFD 2017). Mortality at one year following a hip fracture is approximately 30%; however, fewer than half of deaths are attributable to the fracture itself, reflecting the frailty of the patients and associated high prevalence of comorbidities and complications (Parker 1991; SIGN 2009). Morbidity associated with hip fractures is similar to stroke in terms of impact, with a substantial loss of healthy life-years in older people (Griffin 2015). As such, hip fractures commonly result in reduced mobility and greater dependency, with many people failing to return to their pre-injury residence. In addition, the public health impact of hip fractures is significant: data from large prospective cohorts show

the burden of disease due to hip fracture is 27 disability-adjusted life years (DALYs) per 1000 individuals, which equates to an average loss of 2.7% of the healthy life expectancy in this population at risk of fragility hip fracture (Papadimitriou 2017).

The direct economic burden of hip fractures is also substantial. Hip fractures are among the most expensive conditions seen in hospitals, with an aggregated cost of nearly USD 4.9 billion for 316,000 inpatient episodes in the USA in 2011 (Torio 2011). In England, Wales, and Northern Ireland, hip fracture patients occupy 1.5 million hospital bed days each year, and cost the National Health Service (NHS) and social care GBP 1 billion (NHFD 2017). Combined health and social care costs incurred during the first year following a hip fracture have been estimated at USD 43,669, which is greater than the cost for non-communicable diseases such as acute coronary syndrome (USD 32,345) and ischaemic stroke (USD 34,772) (Williamson 2017). In established market economies, hip fractures represent 1.4% of the total healthcare burden (Johnell 2004).

#### Types of hip fracture

Hip fractures either involve the region of the femur that is enveloped by the ligamentous hip joint capsule (intracapsular), or that is outside the capsule (extracapsular).

Intracapsular fractures include subcapital (immediately below the femoral head), transcervical (across the mid-femoral neck), or basicervical (across the base of the femoral neck). These injuries are also commonly termed fractures of the 'neck of femur' (Lloyd-Jones 2015). Intracapsular fractures can be further subdivided by fracture morphology using several different classification systems, such as the Garden (Garden 1961) or Pauwels classifications (Pauwels 1935). The reliability of these various classifications is poor (Parker 1993; Parker 1998). A more appropriate grouping distinguishes only those fractures that are displaced, where the anatomy of the bone has been disrupted at the fracture site, and those that are undisplaced (Blundell 1998; Parker 1999). This system broadly corresponds with prognosis; the more displaced, the more likely the blood supply to the femoral head is compromised, which can lead to complications such as avascular necrosis and collapse of the femoral head. Furthermore, displaced fractures are less stable, so that treatments involving fixation have a higher risk of failure compared with displaced fractures. Approximately 60% of hip fractures are intracapsular, of these approximately 70% to 90% are displaced (Keating 2010; NHFD 2017).

Extracapsular fractures traverse the femur within the area of bone bounded by the intertrochanteric line proximally up to a distance of 5 cm from the distal part of the lesser trochanter. Several classification methods have been proposed to define different types of extracapsular fractures (AO Foundation 2018; Evans 1949; Jensen 1980). They are generally subdivided depending on their relationship to the greater and lesser trochanters, the two bony projections present at the upper end of the femur, and the complexity of the fracture configuration. It is increasingly clear that each of these classifications is limited in its generalisability since inter- and intra-observer agreement is poor. Table 1 provides a description of the most recent classification of trochanteric fractures (AO Foundation 2018). For this Cochrane Review, we plan to use a pragmatic simplification of these classifications as follows.

- Trochanteric fractures: those that lie mostly between the intertrochanteric line and a transverse line at the level of the lesser trochanter. These can be further divided into simple two-part stable fractures and comminuted or reverse obliquity unstable fractures.
- Subtrochanteric fractures: those that mostly lie in the region bordered by the lesser trochanter and 5 cm distal to the lesser trochanter.

Approximately 40% of hip fractures are extracapsular, of which 90% are trochanteric and 10% are subtrochanteric (NHFD 2017).

## Description of the intervention

Internationally, many guidelines exist concerning hip fracture management (e.g. AAOS 2014; NICE 2011; SIGN 2009). Each recommends that early surgical management, generally within 24 to 48 hours, is the mainstay of care for most hip fractures. The overall goal of surgery in the older population is to facilitate early rehabilitation, enabling early mobilisation and the return to pre-morbid function while minimising the complication risk. This approach has been associated with reductions in mortality in many worldwide registries (Neufeld 2016; Sayers 2017). A proposed grouping of arthroplasty interventions is given in Table 2.

### Arthroplasty

Arthroplasty entails replacing part or all of the hip joint with an endoprosthesis: an implant constructed of non-biological materials such as metal, ceramic, or polyethylene. Arthroplasties can be grouped into two main categories: hemiarthroplasty (HA) where only the femoral head and neck are replaced, and total hip replacement (THR) where both the femoral head and the acetabulum or socket are replaced.

### Hemiarthroplasty

Hemiarthroplasty involves replacing the femoral head with a prosthesis whilst retaining the natural acetabulum and acetabular cartilage. The type of HA can be broadly divided into two groups: unipolar and bipolar. In unipolar HAs, the femoral head is a solid block of metal. Bipolar femoral heads include a single articulation that allows movement to occur, not only between the acetabulum and the prosthesis, but also at this joint within the prosthesis itself.

The best known of the early HA designs are the Moore prosthesis (1952) and the FR Thompson Hip Prosthesis (1954). These are both monoblock implants and were designed before the development of polymethylmethacrylate bone cement. They were therefore originally inserted as a 'press fit'. The Moore prosthesis has a femoral stem, which is fenestrated and also has a square stem with a shoulder to enable stabilisation within the femur; this resists rotation within the femoral canal. It is generally used without cement and, in the long term, bone in-growth into the fenestrations can occur. The Thompson prosthesis has a smaller stem without fenestrations and now often used in conjunction with cement. Numerous other designs of unipolar HAs exist based on stems that have been used for THRs.

In bipolar prostheses, there is an articulation within the femoral head component itself. In this type of prosthesis there is a spherical inner metal head with a size between 22 to 36 mm in diameter. This fits into a polyethylene shell, which in turn is enclosed by a metal cap. The objective of the second joint is to reduce acetabular wear

by promoting movement at the intraprosthetic articulation rather than with the native acetabulum. There are a number of different types of prostheses with different stem designs. Examples of bipolar prostheses are the Charnley-Hastings, Bateman, Giliberty, and the Monk prostheses, but many other types with different stem designs exist.

### Total hip replacement

Total hip replacement involves the replacement of the acetabulum in addition to the femoral head. The first successful THR was developed by John Charnley, using metal alloy femoral heads articulating with polyethylene acetabular components. Subsequently the articulating materials have diversified and designs using metal alloys, ceramics, and various polyethylenes in various combinations have all been used.

### Component fixation

Irrespective of the nature of the articulating surfaces, the components must be fixed to the bone to ensure longevity of the arthroplasty. The two approaches used to achieve this fixation are cemented and uncemented designs.

### Cemented systems

Polymethylmethacrylate bone cement may be inserted at the time of surgery. It sets hard and acts a grout between the prosthesis and the implant the time of surgery. Potential advantages of cement are a reduced risk of intraoperative fracture, later peri-prosthetic fracture and not relying on integration of the prosthesis with osteoporotic bone. Major side effects of cement are cardiac arrhythmias and cardiorespiratory collapse, which occasionally occur following its insertion. These complications may be fatal. The cause of this is either embolism from marrow contents forced into the circulation (Christie 1994), or a direct toxic effect of the cement.

### Uncemented systems

Uncemented systems rely on osseous integration forming a direct mechanical linkage between the bone and the implant. A prosthesis may be coated with a substance, such as hydroxyapatite, which promotes bone growth into the prosthesis. Alternatively, the surface of the prosthesis may be macroscopically and microscopically roughened so that bone grows onto the surface of the implant.

The complications of arthroplasty are those that are general to surgical management of hip fracture, e.g. pneumonia, venous thromboembolism, infection, acute coronary syndrome, and cerebrovascular accident; and those that are specific to arthroplasty including dislocation of the prosthesis, loosening of the components, acetabular wear, and periprosthetic fracture.

## Why it is important to do this review

This review will replace the Cochrane Review, Parker 2010, on the same topic. We will use up-to-date review methods and optimise current relevance in terms of patient population, implants used, and outcomes for policymaking bodies such as the National Institute for Health and Care Excellence (NICE) in the UK, as well as international audiences. Since Parker 2010, clinical uncertainty remains as to the optimum implant for this patient population; moreover, further studies have been reported since the last literature search in September 2009.

Appraisal and synthesis of contemporary evidence may enable more robust conclusions to be made to better inform practice. Furthermore, for displaced intracapsular fractures, the recommended treatment is either HA or total hip arthroplasty (THA) (Parker 2010; Hopley 2010; NICE 2011). However, there is a lack of evidence regarding whether this patient group experiences better outcomes with THA and HA. Recent research has also found interhospital variation and systematic inequalities observed in the provision of THA (Perry 2016). Further evidence is necessary to verify which patients gain the most from THA. For treatment of undisplaced intracapsular fractures, there is also a gap in the evidence that resulted in the recently updated NICE guideline being unable to make an evidence-based recommendation on the best surgical management strategy (NICE 2011). Other reviews are in preparation that will address other types of interventions; we will focus on arthroplasty in this review.

## OBJECTIVES

To determine the relative effects (benefits and harms) of different designs, articulations, and fixation techniques of arthroplasties for treating hip fractures in adults.

This will include assessment of the relative effects (benefits and harms) of the following.

- THR versus HA
- Cemented versus uncemented arthroplasties
- Alternative articulation designs in THA
- Different designs of HA, e.g. bipolar versus unipolar

## METHODS

### Criteria for considering studies for this review

#### Types of studies

We will include randomised controlled trials (RCTs) and quasi-RCTs that assess surgical interventions for the management of patients with hip fracture. Quasi-RCTs are defined as trials in which the methods of allocating people to a trial are not properly random, but were intended to produce similar groups when used to allocate participants (Cochrane 2018). We will include trials published as conference abstracts provided the trial authors report sufficient data relating to the methods and outcomes of interest. Unpublished data will also be considered for inclusion.

#### Types of participants

##### Population

In order to report the generality of evidence available for these patients, we plan to take a wide and pragmatic approach to defining the eligibility criteria. We will report the details of the population in detail in the 'Characteristics of included studies' table.

As a benchmark, thus representative of the general hip fracture population, we would expect trial populations to have a mean age of between 80 to 85 years, and include 70% women, 30% with chronic cognitive impairment, and 50% with an American Society of Anesthesiologists (ASA) score greater than 2 (NHFD 2017; NICE 2011).

### Inclusion criteria

- All adults undergoing surgery for a fragility (low energy trauma) hip fracture, whether intracapsular or extracapsular

### Exclusion criteria

Studies focusing exclusively on the treatment of the following.

- Patients younger than 16 years
- Patients with fractures caused by specific pathologies other than osteoporosis
- Patients with high energy fractures

Studies with mixed populations (fragility and other mechanisms, ages, fracture subtypes, or pathologies) will also be eligible for inclusion. Where data are reported separately, we will extract those subgroup data. Where a study has a mixed population, but subgroups are not reported, the proportion of patients who have standard fragility fracture is likely to hugely outnumber the numbers with high energy or local pathological fractures; therefore the results will be generalisable to fragility fracture population. We will consider sensitivity analyses, where possible, to test this assumption (see [Sensitivity analysis](#)).

We will not pool studies in which the fracture type is mixed (intracapsular and extracapsular).

### Healthcare setting

The expected healthcare setting will be hospitals where operative acute care is undertaken.

### Types of interventions

All hip prostheses: unipolar HA, bipolar HA, or THR (small and large head), applied with or without cement.

### Comparisons

- Prostheses inserted with cement versus without cement (stratified by THR versus HA; HA group subgrouped by modern versus old uncemented stems)
- Bipolar HA versus unipolar HA
- HAs with each other (subgrouped by modern stem design ('ODEP 3A rating') and old stem design (e.g. Austin Moore or Thompson) (new comparison)
- THR versus HA (cemented or uncemented, subgrouped by old versus new as per above)
- Single versus multiple (dual/triple) articulations of THR
- Large-head THR (36 mm diameter or larger) versus other arthroplasty (stratified by THR versus HA)

Direction of comparison: in each comparison, the intervention is named first and the control second.

We plan to create a more detailed table of interventions, grouping them into those that can be reasonably grouped and indicating which are in worldwide use. We will perform this with clinical authors and with the International Fragility Fracture Network ([www.fragilityfracturenetwork.org/](http://www.fragilityfracturenetwork.org/)). A preliminary exercise resulted in the proposed implant groupings given in [Table 2](#).



## Types of outcome measures

### Critical outcomes

We will extract information on the following seven 'critical' outcomes, where reported. These are listed in alphabetical order below. Depending on the length of follow-up reported, the endpoints for each of these outcomes will be categorised into early (up to and including 4 months) and late (after 4 months). We have selected 4 months as the definition of early because most of early recovery has been achieved at this timepoint (Griffin 2015). This is also in accordance with the core outcome set for hip fracture, which prioritises early outcome over late recovery (Haywood 2014). Although priority will be given to outcome at 4 months, we will consider data availability in our selection of data for presentation.

- Activities of daily living (e.g. Barthel Index (BI), Functional Independence Measure (FIM))
- Delirium using recognised assessment scores, such as Mini mental test score or 4AT
- Functional status (region specific) (e.g. hip rating questionnaire, Harris Hip Score, Oxford Hip Score)
- Health-related Quality-of-Life (HRQoL) (e.g. SF36, EQ-5D)
- Mobility (e.g. indoor/outdoor walking status, Cumulated Ambulation Score, Elderly Mobility Scale Score, Timed up and go, Short Physical Performance Battery, self-reported walking scores (e.g. Mobility Assessment Tool - short form))
- Mortality
- Unplanned return to theatre: secondary procedure required for a complication resulting directly or indirectly from the index operation/primary procedure

### Other important outcomes

We will also report the following 'important' outcomes. Where relevant, we will also categorise these into early (up to and including 4 months) and late (after 4 months).

- Pain (verbal rating or visual analogue scale)
- Length of in-hospital stay (LOS)
- Discharge destination. This may be variably defined in the included studies. We will use the study authors' definitions and report all events without a time limit
- Adverse events

We will group adverse events by relatedness to the implant or fracture, or both. We will report each adverse event type separately for maximum clarity. We anticipate that events may include the following.

#### Related

- Damage to a nerve, tendon, or blood vessel
- Intraoperative peri-prosthetic fracture
- Postoperative peri-prosthetic fracture
- Loosening of prosthesis
- Wound infection (as defined by trial investigators, often infection is described as deep or superficial)
- Dislocation

#### Unrelated

- Acute kidney injury

- Blood transfusion
- Cerebrovascular accident
- Chest infection/pneumonia
- Decreased cognitive ability
- Myocardial infarction/acute coronary syndrome
- Sepsis
- Urinary tract infection
- Venous thromboembolic phenomena

## Search methods for identification of studies

We will search for all published, unpublished, and ongoing relevant RCTs, without restrictions on language or date. Where possible, we will remove animal studies using the strategy.

We will develop general search strategies for the large bibliographic databases to find records to feed into a number of Cochrane Reviews on hip fracture surgery. We will use three approaches to identify eligible studies. The approaches are described conceptually as:

1. Hip fractures AND RCT filter;
2. Hip replacement AND fractures AND RCT filter;
3. Internal fixtures AND hip fractures AND RCT filter;
4. 1 OR 2 OR 3.

In MEDLINE, we will use the Cochrane Highly Sensitive Search Strategy for identifying randomised trials (Lefebvre 2018). In Embase, we will use the Cochrane Embase filter to focus on RCTs ([www.cochranelibrary.com/central/central-creation](http://www.cochranelibrary.com/central/central-creation)).

### Electronic searches

We will search the following electronic databases:

- Cochrane Central Register of Controlled Trials (CENTRAL)
- MEDLINE ALL (Ovid)
- Embase (Ovid)
- Science Citation Index (Web of Science)
- Cochrane Database of Systematic Reviews (CDSR) (Cochrane Library)
- Database of Abstracts of Reviews of Effects (DARE) (CRD website)
- Health Technology Assessment (HTA) database (CRD website)
- Epistemonikos ([www.epistemonikos.org/](http://www.epistemonikos.org/))
- ClinicalTrials.gov (<https://clinicaltrials.gov/>)
- WHO ICTRP ([www.who.int/ictip/en/](http://www.who.int/ictip/en/)).

As CENTRAL is kept fully up-to-date with all records from the BJMT Group's Specialised Register, we do not plan to search the latter separately.

The search strategies for the above databases will be modelled on the search strategy designed for MEDLINE (Appendix 1), where possible. Adaptation includes consideration of database interface differences as well as adaptation to different indexing languages. We will document the final search strategies for each of the databases searched in the published review.

## Searching other resources

We will search for unpublished research, conference reports, and research reported in the grey literature by searching a range of resources including the following.

- Handsearching abstracts from the following conferences (2016 to present):
  - \* Fragility Fractures Network Congress
  - \* British Orthopaedic Association Congress
  - \* Orthopaedic World Congress (SICOT)
  - \* Orthopaedic Trauma Association Annual Meeting
  - \* Bone and Joint Journal Orthopaedic Proceedings
  - \* American Academy of Orthopaedic Surgeons Annual Meeting
- Proquest Dissertations and Theses
- National Technical Information Service (NTIS, for technical reports)

To identify further studies, we will screen the reference lists of eligible studies and systematic reviews published within the last five years that have been retrieved by the searches. We will screen the reference lists of relevant Cochrane Reviews that are being updated, irrespective of the date they were published.

## Data collection and analysis

Any review author who is a co-applicant, author or has or has had an advisory role on any potentially relevant study, will remain independent of study selection decisions, risk of bias assessment and data extraction for their study.

### Selection of studies

Two review authors will screen the titles and abstracts of all retrieved bibliographic records using the internet-based systematic reviewing platform, Rayyan ([Ouzzani 2016](#)). Two review authors will retrieve and independently examine the full texts of all potentially eligible records after title/abstract screening using the eligibility criteria (see [Criteria for considering studies for this review](#)). We will perform full-text screening using the internet-based platform Covidence ([Covidence](#)). Disagreements will be resolved by discussion or adjudication by a third review author. Where necessary, we will correspond with study authors where clarification is required to inform study selection. We will exclude duplicates and will collate multiple reports of the same study so that each study, rather than each report, is the unit of interest in the review. We will construct a PRISMA flow-diagram ([Moher 2009](#)), which will outline the study selection process, numbers of records at each stage of selection, and reasons for exclusions of full-text articles. Details will also be recorded in a 'Characteristics of excluded studies' table.

### Data extraction and management

Two review authors will independently extract data using a prepiloted structured form to ensure consistency of information and appraisal of each study. They will independently pilot the form on at least one included study before implementation. The two review authors will ascertain that data are entered correctly into the final data set. We will extract data on the following.

## Study methodology

Publication type, sponsorship and funding for the trial and any notable conflicts of interest of trial authors, study design, trial phase, number of centres and location(s), size and type of setting (e.g. in-hospital or out-of-hospital or mixed or community), study period and length of follow-up, stated study objectives, study inclusion and exclusion criteria, randomisation method, masking, study disposition (number randomised, number by protocol, number available for analysis).

### Population

We will extract information on baseline characteristics of the participants, including age, gender, comorbidities, functional status (such as previous mobility), fracture type and displacement, and cognitive status.

### Interventions

We plan to extract data concerning the exact nature of the interventions tested and any reported co-interventions. We will also extract information, where available, on any co-interventions, such as preoperative care (e.g. prophylaxis - antibiotics, venous thromboembolism, delirium), anaesthetic management, and postoperative care (e.g. rehabilitation).

### Outcome data

Where possible, we will extract data by arm rather than the summary effect sizes. Outcome worksheets will be in 'one study per row format' and will specify the number of arms for each study and number of participants in each arm; numbers randomised and analysed for each outcome at each timepoint; number of events in each arm (for rate, binary or categorical data); and means and standard deviations, effect measures, point estimates and confidence limits (for continuous variables). Where available, we will split the outcomes into early and late as described.

### Assessment of risk of bias in included studies

We will assess the risk of bias in the included studies using the tool described for standard systematic reviews in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011a](#)). Two review authors will independently perform these assessments and will resolve any discrepancies through discussion or by consulting a third review author. Where details of methods are unclear or not reported, we will contact the study authors for additional information.

We will evaluate the risk of bias in the following domains: selection bias (random sequence generation and allocation concealment), performance bias (blinding of participants and personnel), detection bias (blinding of outcome assessment), attrition bias (incomplete outcome data), reporting bias (selective reporting), and other bias. We will assess each potential source of bias as either high, low, or unclear and will provide a quote from the study report together with a justification for our judgement in the 'Risk of bias' table. The 'Risk of bias' judgements will be summarised across different studies for each of the domains listed.

Assessment of risk of bias is specific to a particular result for a particular outcome (and time point) in the study. However, some domains will apply generally to the whole study (such as random sequence generation and allocation concealment); some will apply



mainly to the outcome being measured or measurement method being used (such as blinding of participants and personnel, and blinding of outcome assessment); and some will apply to the specific result (such as selective reporting bias).

In the domains specific to particular outcomes, we will provide considerations of risk of bias for different types of outcomes and will make assessments separately. For example, for participant reported outcomes (e.g. pain, HRQoL), observer reported outcomes not involving judgement (e.g. all-cause mortality), observer reported outcomes involving some judgement (e.g. assessment of a radiograph, clinical examination, and clinical events other than death), outcomes that reflect decisions made by the intervention provider (e.g. hospitalisation, stopping treatment, referral to a different ward and discharge of the patient), and composite outcomes (e.g. major cardiac and cerebrovascular events (MACCE)).

As trials frequently contribute multiple results, mainly through contributing to multiple outcomes, several 'Risk of bias' assessments may be needed for each study. These assessments are likely to align with the outcomes included in a 'Summary of findings' table.

### Measures of treatment effect

Where sufficiently reported, we will analyse data on an intention-to-treat (by allocated groups irrespective of compliance) basis.

We will calculate risk ratios (RR) for dichotomous data outcomes with 95% confidence intervals (CIs). Where the number of observed events is small (less than 1% of sample per group or with zero events in either arm), and where trials have balanced treatment groups, we will report the Peto odds ratio (OR) with 95% CI (Deeks 2017). We will express treatment effects for continuous data outcomes as mean differences (MD) with 95% CI; if the outcomes are measured using different scales, we will use standardised mean differences (SMD) with 95% CI.

### Unit of analysis issues

We anticipate that the patient will be the unit of analysis. We do not expect to encounter any within-person randomised trials or cluster-randomised trials. If we do identify any, we will treat them in accordance with the guidance in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b). We expect outcomes to be reported at various timepoints. We have specified short-term and long-term follow-up analyses in the [Types of outcome measures](#) section. We will also treat multi-arm trials in accordance with the advice given in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b).

### Dealing with missing data

We will contact the study authors to attempt to obtain missing data or to clarify unclear data. For each included study, we will record the number of participants lost to follow-up. Our primary analysis will be a complete-case analysis; we do not plan to impute missing data. However, if large amounts of data are missing, we will consider exploratory sensitivity analyses to investigate possible effects of the missingness (see [Sensitivity analysis](#)). Where study authors do not report standard deviations, we will try to determine these from standard errors, CIs, or exact P values.

### Assessment of heterogeneity

We will use the  $I^2$  statistic, automatically calculated in the Review Manager 5 software (Review Manager 2014), to quantify the possible degree of heterogeneity of treatment effects between trials. We will assume moderate heterogeneity when the  $I^2$  statistic value is between 30% and 60%; substantial heterogeneity when it is between 50% and 90%; and considerable heterogeneity when it is between 75% and 100%. We will keep in mind that the importance of the  $I^2$  statistic value depends on: 1) magnitude and direction of effects; and 2) strength of evidence for heterogeneity. If we identify substantial heterogeneity, we will report it and investigate possible causes by following the recommendations in Section 9.6 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2017).

We will assess clinical and methodological diversity in terms of participants, interventions, outcomes, effect modifiers, and study characteristics for the included studies to determine whether a meta-analysis is appropriate. We will conduct this by observing these data from the data extraction tables.

We will then visually inspect the forest plot to look at the consistency of intervention effects across included studies. If the studies are estimating the same intervention effect, there should be overlap between the CIs for each effect estimate on the forest plot. However, if overlap is poor or there are outliers, statistical heterogeneity may be likely.

### Assessment of reporting biases

Where sufficient numbers of studies (more than 10) are available for meta-analysis, we will construct a funnel plot to identify potential for publication bias as well as to explore possible small study biases. In interpreting funnel plots, we will examine the different reasons possible for funnel plot asymmetry and relate this to the results of the review. We will also undertake formal statistical tests to investigate funnel plot asymmetry, and will follow the recommendations in Section 10.4 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Sterne 2017).

To assess outcome reporting bias, we will check trial protocols against their published reports. We will also screen clinical trial registries for a priori trial protocols. We will evaluate whether selective reporting of outcomes is present.

### Data synthesis

We will undertake meta-analyses only where this is meaningful, that is, if the treatments, participants, and the underlying clinical question are similar enough for pooling to make sense. When considered appropriate, we will pool results of comparable groups of trials using random-effects models. We chose this model after careful consideration of the extent to which any underlying effect could truly be thought to be fixed given the complexity of the interventions included in this review. We will present 95% CIs throughout.

We will consider not pooling data where there is considerable heterogeneity ( $I^2$  statistic value of greater than 75%) that cannot be explained by the diversity of methodological or clinical features among trials. We will still present trial data in the analyses or tables for illustrative purposes and report these in the text.

We will not pool multiple component interventions together with studies that report comparisons of only a single intervention. We will group any relevant studies by the combination of interventions (i.e. where the same combination of single categories of intervention is delivered to all participants). We will analyse each combination separately.

When considered appropriate, we will pool data using the generic inverse variance method in Review Manager 5 ([Review Manager 2014](#)). This method enables pooling of the adjusted and unadjusted treatment effect estimates reported in the individual studies or that can be calculated from data presented in the published article (see [Measures of treatment effect](#)). The generic inverse variance option in Review Manager 5 requires entering the natural logarithm of the treatment effect and its standard error for each trial ([Review Manager 2014](#)).

### Subgroup analysis and investigation of heterogeneity

If sufficient number of studies meet the inclusion criteria, we will explore (as possible sources of inconsistency or heterogeneity between studies) key confounders, such as age (cut-off 85 years), gender, cognitive impairment, and fracture type (e.g. displaced versus minimally displaced and extracapsular versus intracapsular fractures). We also have some pre-specified comparison-specific subgroups.

We will investigate whether the results of subgroups are significantly different by inspecting overlapping CIs and by performing the test for subgroup differences available in Review Manager 5 ([Review Manager 2014](#)), where appropriate.

There is no explicit means of accounting for step changes in co-interventions, and certainly not one that would be applicable to the worldwide totality of the evidence. Therefore we cannot try to explain any heterogeneity by statistical test of subgroups defined by co-intervention we will order forest plots by date of recruitment so we can visually inspect and comment on any temporal trend.

### Sensitivity analysis

If a sufficient number of studies meet the inclusion criteria, we will assess the effect of excluding the following types of studies.

- At high risk of bias
- Have substantial amounts of missing data
- Have quasi methods of randomisation

- Have mixed population
- Report interventions that are not currently in clinical use

### GRADE assessment and 'Summary of findings' tables

Two review authors will independently assess the certainty of evidence for each of the seven primary ('critical') outcomes using the GRADE approach developed by the international GRADE working group ([www.gradeworkinggroup.org/](http://www.gradeworkinggroup.org/)). We will use the software developed by the GRADE working group, [GRADEpro GDT 2015](#), to assess the certainty of the evidence for each outcome, taking into account individual study factors and the meta-analysis results. We will also present the results and the certainty of evidence for the main outcomes in a 'Summary of findings' table using GRADEpro GDT software ([Schünemann 2019](#)).

The chosen outcomes are those we consider to be most clinically important and useful for readers; these are described under 'Critical outcomes' in the [Types of outcome measures](#) section. We will consider the GRADE domains: risk of bias, inconsistency, indirectness, imprecision, and publication bias ([Guyatt 2008](#)). We will resolve any disagreements by consulting a third review author. The certainty of the evidence could be either high, moderate, low, or very low; being downgraded by one or two levels depending on the presence and extent of the five GRADE domains. We will use footnotes to describe the reasons for grading a domain as having 'serious' or 'very serious' problems and we will make further comments to aid the reader's understanding of the 'Summary of findings' table where necessary. We will consider the certainty of the evidence and the effect when making conclusions. We will also provide rationale for the figure used to calculate the assumed risk in a footnote.

We will provide further details on the full methods used for GRADE assessment of outcomes in an appendix in the published review.

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## ADDITIONAL TABLES

**Table 1. Trochanteric region fractures: type and surgical management (revised AO/OTA classification, January 2018)**

Type	Features	Stability	Description
Simple, pertrochanteric fractures (A1)	<ul style="list-style-type: none"> <li>Isolated pertrochanteric fracture</li> <li>2-part fracture</li> <li>Lateral wall intact</li> </ul>	Stable	The fracture line can begin anywhere on the greater trochanter and end either above or below the lesser trochanter. The medial cortex is interrupted in only 1 place.
Multifragmentary pertrochanteric fractures (A2)	<ul style="list-style-type: none"> <li>With 1 or more intermediate fragments</li> <li>Lateral wall may be incompetent</li> </ul>	Unstable	The fracture line can start laterally anywhere on the greater trochanter and runs towards the medial cortex which is typically broken in 2 places. This can result in the detachment of a third fragment which may include the lesser trochanter.
In-trochanteric fractures (A3)	<ul style="list-style-type: none"> <li>Simple oblique fracture</li> <li>Simple transverse fracture</li> <li>Wedge or multifragmentary fracture</li> </ul>	Unstable	The fracture line passes between the 2 trochanters, above the lesser trochanter medially and below the crest of the vastus lateralis laterally.

AO/OTA: Arbeitsgemeinschaft für Osteosynthesefragen (German for "Association for the Study of Internal Fixation") / Orthopaedic Trauma Association

**Table 2. Possible grouping of different types of arthroplasty for hip fracture in adults**

Implant category	Variable (articulation/fixation)	Implant subcategory	Examples <sup>a</sup>	Description

## Arthroplasties for hip fracture in adults (Protocol)

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**Table 2. Possible grouping of different types of arthroplasty for hip fracture in adults** (Continued)

Table 2: Possible grouping of different types of arthroplasty for hip fracture in adults (continued)				
Total hip arthroplasty	Articulation	Femoral head and acetabular bearing surface materials	<ul style="list-style-type: none"><li>• Metal-on-polyethylene (MoP)</li><li>• Ceramic-on-polyethylene (CoP)</li><li>• Ceramic-on-ceramic (CoC)</li><li>• Metal-on-metal (MoM)</li><li>• Polyethylene material</li><li>• Highly cross linked (HCL)</li><li>• Not HCL</li></ul>	Bearing surfaces may be grouped into hard (ceramic and metal) and soft (polyethylene variants). Arthroplasties exist with many of the possible combinations of these bearing surfaces.
		Femoral head size	<ul style="list-style-type: none"><li>• Large head ≥ 36 mm</li><li>• Standard small head &lt; 36 mm</li></ul>	Over the development of hip arthroplasty different sizes of femoral head have been used from 22 mm to very large diameters approximating that of the native femoral head. The size of the head represents a compromise between stability and linear and volumetric wear at the articulation. The optimum size varies by indication and bearing materials. 36 mm is considered as a cut-off between standard and large sizes.
		Acetabular cup mobility	<ul style="list-style-type: none"><li>• Single</li><li>• Dual</li></ul>	A standard THA has a single articulating surface between the femoral head and acetabulum bearing surface. Alternative designs incorporate a further articulation within the structure of the femoral head.
	Fixation technique	Cemented	<ul style="list-style-type: none"><li>• Exeter Hip System</li><li>• CPT Hip System</li></ul>	Both components are cemented with polymethylmethacrylate bone cement that is inserted at the time of surgery. It sets hard and acts a grout between the prosthesis and the bone.
		Modern uncemented	<ul style="list-style-type: none"><li>• Corail Hip System</li><li>• Avenir Hip System</li><li>• Taperloc Hip System</li></ul>	Neither component is cemented but rely on osseous integration forming a direct mechanical linkage between the bone and the implant. The femoral prosthesis may be coated with a substance such as hydroxyapatite which promotes bone growth into the prosthesis. Alternatively, the surface of the prosthesis may be macroscopically and microscopically roughened so that bone grows onto the surface of the implant. The acetabular component may be prepared similarly and may or may not be augmented with screws fixed into the pelvis.
Hybrid		Combinations	The femoral stem is cemented and the acetabular cup is uncemented.	
Reverse hybrid		Combinations	The acetabular cup is cemented and the femoral stem is uncemented	



**Table 2. Possible grouping of different types of arthroplasty for hip fracture in adults** (Continued)

Hemi-arthroplasty	Articulation	Unipolar	<ul style="list-style-type: none"> <li>• Thompson</li> <li>• Austin-Moore</li> <li>• Exeter Trauma Stem</li> <li>• Exeter Uni-trax</li> </ul>	A single articulation between the femoral head and the native acetabulum. The femoral component can be a single 'monoblock' of alloy or be modular, assembled from component parts during surgery.
		Bipolar	<ul style="list-style-type: none"> <li>• CPT modular bipolar</li> <li>• Exeter modular bipolar</li> <li>• Bateman</li> <li>• Monk</li> </ul>	The object of the second joint is to reduce acetabular wear. This type of prosthesis has a spherical inner metal head with a size between 22 to 36 mm in diameter. This fits into a polyethylene shell, which in turn is enclosed by a metal cap. There are a number of different types of prostheses with different stem designs.
	Fixation technique	First generation uncemented	<ul style="list-style-type: none"> <li>• Thompson</li> <li>• Austin-Moore</li> </ul>	These prostheses were designed before the development of polymethylmethacrylate bone cement and were therefore originally inserted as a 'press fit'. Long-term stability through osseous integration was not part of the design concept.
		Cemented	<ul style="list-style-type: none"> <li>• Thompson</li> <li>• Exeter Trauma Stem</li> <li>• Exeter Hip System</li> <li>• CPT Hip System</li> </ul>	The femoral stem is cemented with polymethylmethacrylate bone cement that is inserted at the time of surgery. It sets hard and acts a grout between the prosthesis and the bone.
		Modern uncemented	<ul style="list-style-type: none"> <li>• Corail</li> <li>• Furlong</li> <li>• Avenir</li> </ul>	The femoral stem relies on osseous integration forming a direct mechanical linkage between the bone and the implant. A prosthesis may be coated with a substance such as hydroxyapatite, which promotes bone growth into the prosthesis. Alternatively, the surface of the prosthesis may be macroscopically and microscopically roughened so that bone grows onto the surface of the implant.

<sup>a</sup>This list is not exhaustive. In the Cochrane Review, we will include any implant tested in included trials not already listed here.

Abbreviations:

CoC: Ceramic-on-ceramic

CoP: Ceramic-on-polyethylene

CPT: collarless polished tapered

HCL: Highly cross linked

MoM: Metal-on-metal

MoP: Metal-on-polyethylene

THA: total hip arthroplasty

## APPENDICES

### Appendix 1. MEDLINE search strategy

#### Ovid interface

1 exp Femoral Fractures/

2 ((hip or hips or cervical) adj5 (fracture\$ or break\$ or broke\$)).ti,ab,kf.

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3 ((femoral\$ or femur\$ or acetabul\$) adj5 (fracture\$ or break\$ or broke\$)).ti,ab,kf.  
4 ((intracapsular or intra-capsular or subcapital or sub-capital or transcervical or trans-cervical or basicervical or basi-cervical) adj5 (fracture\$ or break\$ or broke\$)).ti,ab,kf.  
5 ((extracapsular or extra-capsular or trochant\$ or subtrochant\$ or pertrochant\$ or intertrochant\$) adj5 (fracture\$ or break\$ or broke\$)).ti,ab,kf.  
6 (((head or neck or proximal) adj5 (fracture\$ or break\$ or broke\$)) and (femoral\$ or femur\$)).ti,ab,kf.  
7 or/1-6  
8 randomized controlled trial.pt.  
9 controlled clinical trial.pt.  
10 randomized.ab.  
11 placebo.ab.  
12 clinical trials as topic.sh.  
13 randomly.ab.  
14 trial.ti.  
15 8 or 9 or 10 or 11 or 12 or 13 or 14  
16 7 and 15  
17 Arthroplasty, Replacement, Hip/ or Hip Prosthesis/  
18 Arthroplasty, Replacement/ or Hemiarthroplasty/ or Joint Prosthesis/  
19 (arthroplast\$ or hemiarthroplast\$).ti,ab,kf.  
20 ((hip or hips) adj5 (replac\$ or prosthes\$ or implant\$)).ti,ab,kf.  
21 ((joint\$1 adj5 (replac\$ or prosthes\$ or implant\$)) and (hip or hips or femur\$ or femoral\$ or acetabul\$)).ti,ab,kf.  
22 or/17-21  
23 fractures, bone/ or exp fracture dislocation/ or fractures, closed/ or fractures, comminuted/ or fractures, compression/ or fractures, malunited/ or fractures, multiple/ or fractures, open/ or fractures, spontaneous/ or exp fractures, stress/ or fractures, ununited/ or intra-articular fractures/ or osteoporotic fractures/ or periprosthetic fractures/ (92406)  
24 fracture\$.ti,ab,kf.  
25 23 or 24  
26 22 and 25 and 15  
27 (pin or pins or nail or nails or screw or screws or plate or plates).ti,ab,kf.  
28 internal fixators/ or bone nails/ or bone plates/ or exp bone screws/  
29 (static adj (device\$1 or implant\$1)).ti,ab,kf.  
30 (dynamic adj (device\$1 or implant\$1)).ti,ab,kf.  
31 or/27-30  
32 ((hip or hips or femur\$ or femoral\$ or acetabul\$) and (fracture\$ or break\$ or broke\$)).ti,ab,kf.  
33 (hip or hips or femur\$ or femoral\$ or acetabul\$).ti,ab,kf. and (fractures, bone/ or exp fracture dislocation/ or fractures, closed/ or fractures, comminuted/ or fractures, compression/ or fractures, malunited/ or fractures, multiple/ or fractures, open/ or fractures, spontaneous/ or exp fractures, stress/ or fractures, ununited/ or intra-articular fractures/ or osteoporotic fractures/ or periprosthetic fractures/)  
34 or/32-33  
35 31 and 34 and 15  
36 16 or 26 or 35  
37 exp animals/ not humans/  
38 36 not 37

## CONTRIBUTIONS OF AUTHORS

AS (systematic reviewer): drafted the protocol, reviewed, and approved the final protocol.

MP (content expert, Orthopaedics): drafted the protocol, reviewed, and approved the final protocol.

HW (senior information specialist): designed the search strategies, reviewed, and approved the final protocol.

JMG (senior information specialist): designed the search strategies, drafted the protocol, reviewed, and approved the final protocol.

JC (statistician): reviewed and approved the final protocol.

XG (content expert, Trauma and Orthopaedics): drafted the protocol, reviewed and approved the final protocol, and is the guarantor of the content.

## Contributions of the editorial base

Helen Handoll (Co-ordinating Editor): edited the protocol, advised on methodology and protocol content, and approved the final version for publication.

Joanne Elliott (Managing Editor): coordinated the editorial process, advised on content, and edited the protocol.

Maria Clarke (Information Specialist): checked the search methods section.

## DECLARATIONS OF INTEREST

AS: has no known conflicts of interest.

MP: has received expenses and honorarium from a number of commercial companies and organisations for giving lectures on different aspects of hip fracture treatment. In addition, he has received royalties from BBraun Ltd related to the design and development of an implant used for the internal fixation of intracapsular hip fractures.

HW: has no known conflicts of interest.

JMG: has no known conflicts of interest.

JC: has no known conflicts of interest.

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