

# Efficacy of total hip arthroplasty for the treatment of patients with femoral head avascular necrosis

## A protocol for systematic review and meta-analysis

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### Abstract

**Background:** Femoral head avascular necrosis (FHAN) is a very common condition among elderly population. Previous studies have reported that total hip arthroplasty (THAP) can benefit patients with such condition. However, no study systematically addressed this topic. Thus, this study will systematically explore the efficacy and safety of THAP for the treatment of patients with FHAN.

**Methods:** We will search the following electronic bibliographic databases from inception to the February 29, 2020: MEDLINE, EMBASE, Cochrane Library, Cumulative Index to Nursing and Allied Health Literature, China National Knowledge Infrastructure, and Chinese Scientific Journal Database. Randomized controlled trials of THAP for the treatment of patients with FHAN will be included, which were reported in any language. All process of study selection, data collection, and study quality assessment will be performed independently by 2 authors independently. Any divergences will be solved by discussion with another author. RevMan 5.3 software will be carried out for data synthesis and analysis.

**Results:** This study will provide a detailed summary of current evidence related to the efficacy and safety of THAP for the treatment of patients with FHAN through assessing pain intensity of hip or knee joints, function and limitation of attacked femoral head, health-related quality of life, and complications.

**Conclusion:** The findings of this study may provide helpful guidance of THAP for the treatment of patients with FHAN.

**Systematic review registration:** INPLASY202040067.

**Abbreviations:** CIs = confidence intervals, FHAN = femoral head avascular necrosis, RCTs = randomized controlled trials, THAP = total hip arthroplasty.

**Keywords:** complications, efficacy, femoral head avascular necrosis, total hip arthroplasty

## 1. Introduction

Femoral head avascular necrosis (FHAN) is a very common and complicated disorder in osteonecrosis.<sup>[1–5]</sup> It occurs because of the disruption of blood supply to the head of femur.<sup>[6–10]</sup> It has been estimated about 10000 to 20000 new cases reported annually in the USA.<sup>[11]</sup> Although current interventions have

reported to treat FHAN, there is still limited efficacy and thus further cause damage of femoral head.<sup>[12–17]</sup> Fortunately, total hip arthroplasty (THAP) have reported to treat FHAN effectively.<sup>[18–23]</sup> However, no systematic review has been undertaken to assess the efficacy and safety of THAP for FHAN. Therefore, this study will assess the efficacy and safety of THAP for the treatment of patients with FHAN.

XFQ and YX contributed equally to this study.

The authors have no conflicts of interest to disclose.

Data sharing not applicable to this article as no datasets were generated or analyzed during the current study.

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## 2. Methods and analysis

### 2.1. Study registration

We have registered this protocol on INPLASY202040067. We report it following the guideline of Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol statement guidelines.<sup>[24–25]</sup>

### 2.2. Eligibility criteria for study selection

**2.2.1. Types of study.** Randomized controlled trials (RCTs) of THAP for the treatment of patients with FHAN, which were reported in any language, will be included. Any uncontrolled trial, non-RCTs and quasi-RCTs will all be excluded.

**2.2.2. Types of participant.** Participants who were diagnosed as FHAN will be included regardless their age, sex, and source of studies.

### 2.2.3. Types of intervention

**2.2.3.1. Interventions.** Any types of THAP therapy used in patients as interventional intervention will be included in this study.

**2.2.3.2. Comparators.** We will include patients who received any management as a control intervention in this study. We will exclude any combined therapy with THAP as their comparators.

**2.2.4. Types of outcome measurement.** Primary outcome includes pain intensity. It is measured by any validated pain scales, such as Numerical Rating Scale.

Secondary outcomes are function and limitation of attacked femoral head (as checked by any relevant validated indexes, including Western Ontario and McMaster Universities Osteoarthritis Index), health-related quality of life (as evaluated by any related tools, such as 36-Item Short Form Health Survey), and any complications post surgery.

### 2.3. Literature search

The following electronic bibliographic databases will be searched from inception to the February 29, 2020: MEDLINE, EMBASE, Cochrane Library, Cumulative Index to Nursing and Allied Health Literature, China National Knowledge Infrastructure, and Chinese Scientific Journal Database. We will identify any potential RCTs of THAP for the treatment of patients with FHAN. We will search all these electronic databases without any language and publication status restrictions. The search strategy for MEDLINE is presented (Table 1). We will modify similar search strategies to all other electronic databases.

Other resources for potential studies are also searched, such as websites of clinical trial registry, and reference lists of included trials and relevant reviews.

### 2.4. Study selection

The titles/abstracts of all retrieved literatures will be scanned independently by 2 authors based on the predefined eligibility

criteria. All unconnected studies will be removed. If necessary, full text of remaining potential trials will be read cautiously against all inclusion criteria. Any different views on the study selection will be arbitrated by a third author. All excluded literatures will be noted in a table with specific reasons for their exclusion. The study selection process is exerted in a flowchart.

### 2.5. Data extraction and management

The following data will be extracted from all included RCTs by 2 independent authors using predefined data acquisition form: reference ID, author information, publication time, patient characteristics, sample size, study setting, study methods, details of intervention and controls, outcome indicators at all reported time points, complications, follow-up information, results, findings, and conflict of interests. Any different opinions will be arbitrated by a third author through discussion.

### 2.6. Missing data dealing with

If we identify any missing or unclear data, we will connect corresponding authors or relevant authors to obtain it. We will use an intention-to-treat analysis in case of missing data if possible. The potential impacts of missing data will be discussed as a limitation in this study.

### 2.7. Risk of bias assessment

Risk of bias for each eligible trial will be assessed by 2 independent authors using Cochrane Risk of Bias Tool. Two authors will independently judge them for each study on 7 aspects. Each aspect will be categorized as high, unclear or low risk of bias. Any disagreements regarding the risk of bias assessment will be solved by a third author through discussion.

### 2.8. Statistical analysis

RevMan 5.3 software will be used for data synthesis and statistical analysis.

**2.8.1. Treatment effect measurement.** As for dichotomous outcome data (such as incidence of complications), risk ratio and 95% confidence intervals will be employed. As for continuous outcome data (such as pain intensity of hip or knee joints), mean difference or standardized mean difference and 95% confidence intervals will be exerted.

**2.8.2. Heterogeneity assessment.** Statistical heterogeneity will be investigated using  $I^2$  test.  $I^2 \leq 50\%$  means little or no statistical heterogeneity across the included trials, and a fixed-effects model will be practiced.  $I^2 > 50\%$  indicates considerable heterogeneity, and a random-effects model will be utilized.

**2.8.3. Data synthesis.** If statistical heterogeneity is minor among included trials, we will undertake meta-analysis based on the similar study and patient characteristics, interventions, controls, and outcome indicators. If statistical heterogeneity is considerable across the eligible studies, we will perform subgroup analysis to explore possible sources for such heterogeneity. If it is still not possible to conduct meta-analysis after subgroup analysis, we will report outcome results as a narrative summary.

**2.8.4. Subgroup analysis.** If data are available, we will carry out subgroup analysis to explore the sources of considerable

**Table 1**  
Search strategy of MEDLINE.

Number	Search terms
1	Femoral head
2	Avascular necrosis
3	Osteonecrosis
4	Hip joint
5	Blood supply
6	Or 1-5
7	Total hip arthroplasty
8	Total hip replacement
9	Hip replacement surgery
10	Hip arthroplasty
11	Joint replacement
12	Or 7-11
13	Randomized controlled trials
14	Controlled trial
15	Randomly
16	Random
17	Clinical trial
18	Trial
19	Or 13-18
20	6 and 12 and 19

heterogeneity based on the variations in study characteristics, different types of interventions and controls, and outcomes.

**2.8.5. Sensitivity analysis.** We will conduct a sensitivity analysis to monitor the robustness of the study findings based on the methodological weaknesses and missing data.

**2.8.6. Publication bias.** Funnel plot and Egger test will be generated to observe any potential publication biases when at least 10 eligible trials are included in this study.

**2.8.7. Summary of evidence.** Two authors will independently appraise the quality of evidence for main outcome indicators using the Grading of Recommendations Assessment, Development, and Evaluation System approach.<sup>[26–27]</sup> Its results will be demonstrated in the ‘summary of findings’ tables in the final report. Any different views will be solved by a third author through discussion.

### 2.9. Dissemination and ethics

This study does not require ethical approval, because it will not use individual patient data. This study is expected to be published through a peer-reviewed journal.

## 3. Discussion

This study firstly investigated the efficacy and complications of THAP for the treatment of patients with FHAN. The findings of this study will provide a detailed and summary of the existing evidence relevant of THAP in pain relief of knees and hips, function improvements of attacked joints, and health-related quality of life in patients with FHAN.

Moreover, it may also provide helpful reference and recommendation for clinicians and further researches.

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### Author contributions

**Conceptualization:** Xiao-feng Qiao, Qing-hui Ji.

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