INPLASY PROTOCOL

To cite: Qian et al. Efficacy and safety of acupuncture for non-traumatic osteonecrosis of the femoral head: A protocol for systematic review and meta-analysis. Inplasy protocol 202260003. doi: 10.37766/inplasy2022.6.0003

Received: 01 June 2022

Published: 01 June 2022

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Support: **Postgraduate Education Fund.**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None declared.

Efficacy and safety of acupuncture for non-traumatic osteonecrosis of the femoral head: A protocol for systematic review and meta-analysis

Qian, LF[1]; Zhan, HX[2]; Wei, BF[3].

Review question / Objective: **This system review aims to evaluate the efficacy and safety of acupuncture for non-traumatic osteonecrosis of the femoral head and the type of study is randomized controlled trials.**
Condition being studied: **Non-traumatic osteonecrosis of the femoral head (NONFH) is a painful disorder characterized by trabecular bone fracture, bone cell necrosis, and articular surface collapse. The incidence of the NONFH is high in young and middle-aged adults. Its incidence is rising partly due to the widespread clinical use of corticosteroids, and the morbidity rate is high if left untreated. NONFH is one of the world public health problems that have attracted the widespread attention of society.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 June 2022 and was last updated on 01 June 2022 (registration number INPLASY202260003).

INTRODUCTION

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widespread clinical use of corticosteroids, and the morbidity rate is high if left untreated. NONFH is one of the world public health problems that have attracted the widespread attention of society.

METHODS

Participant or population: Patients over 18 years old and diagnosed with NONFH will be included in this study. There will be no restrictions on gender, race, nationality, and education background.

Intervention: We will include studies that received acupuncture treatment alone in the intervention group.

Comparator: The control group was intervened with sham acupuncture or placebo acupuncture. Studies in the combination of acupuncture and another therapy will be included in the review if another therapy was performed equally in both two groups. In addition, there will be no limits to acupoints, frequency, needing techniques, stimulation methods and test cycle.

Study designs to be included: Randomized Controlled Trials

Eligibility criteria: We will include the RCTs of acupuncture therapy for non-traumatic osteonecrosis of the femoral head. The protocol follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) statement guidelines.

Information sources: We will comprehensively search relevant literature via the electronic databases of PubMed, MEDLINE, EMBASE, Cochrane Library, Chinese National Knowledge Infrastructure, Chinese Scientific Journal Database Information, Wanfang Database, and Chinese Biomedical Literature Database from inception to 10 May, 2022. We will also scan the relevant published references carefully to identify further publications. We will include RCTs on assessing the efficacy and safety of acupuncture for NONFH.

Main outcome(s): The primary outcomes include Visual Analog Scale, Numerical Rating Scale, Brief Pain Inventory, and other validated instruments for assessing pain intensity. Studies that reported only improvement rates will be excluded. Secondary outcome indicators include Harris hip score, quality of life, and treatment related adverse events.

Quality assessment / Risk of bias analysis: Two reviewers will evaluate the quality of the included literature according to the guidance from the Cochrane Handbook of Systematic Reviews of Interventions. The methodological quality will be evaluated from the following domains: random sequence generation, allocation concealment, blinding of participants and therapist, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other possible biases. The risk of bias for each study will be categorized as “low risk of bias”, “high risk of bias”, or “unclear risk of bias”.

Strategy of data synthesis: Data extracted from RCTs meeting inclusion criteria will be analyzed using RevMan. The count data will be calculated using Odds Ratio (OR) and 95% confidence interval (CI). If data information is missing or insufficient in the included studies, two reviewers will contact the corresponding author for retrieving the lost data. If the lost data cannot be retrieved, two reviewers will only analyze the available data in the review. Statistical heterogeneity across studies will be estimated using the chi-square test ($p < 0.10$ will be considered representative of significant statistical heterogeneity) and the I2. If the values of I2 are >50%, the significant heterogeneity will be thought to exist. A random effect model will be applied for analysis if statistical heterogeneity existed ($p < 0.10$, I2 >50%). If there is no observed heterogeneity, fixed effect models will be chosen. If the number of included studies is more than 10, funnel plot will be drawn and analyzed by RevMan 5.3 software to evaluate potential publication bias.

Subgroup analysis: If our review shows substantial heterogeneity, we will undertake subgroup analysis for different aspects, such as different methods of acupuncture, different needles, and age and gender of patients.

Sensitivity analysis: Sensitivity analysis will be used to the robustness of the review conclusions. The robustness of the conclusions can be tested by excluding studies with high risk of bias.

Language: The language of the trial is limited to Chinese and English.

Country(ies) involved: China.

Keywords: acupuncture; non-traumatic osteonecrosis of the femoral head; meta-analysis; system review.

Contributions of each author:

Author 1 - Liufen Qian - drafted the manuscript, collected and analyzed the data.
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Author 2 - Huixian Zhan - collected and analyzed the data.
Author 3 - Biaofang Wei - provided the Conceptualization of the study and supervised, reviewed and edited the manuscript.