

INPLASY PROTOCOL

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Support: NSFC.

Review Stage at time of this submission: Preliminary searches.

Conflicts of interest:
None declared.

INTRODUCTION

Review question / Objective: We aimed to systematically review the effectiveness and safety of TCM in the treatment of SONFH.

Effectiveness and safety of traditional Chinese medicine in the treatment of steroid-osteonecrosis of femoral head: A protocol for systematic review and meta-analysis

He, P¹; Chen, J²; Yue, C³; Ma, M⁴; Hong, Z⁵; Liu, Y⁶.

Review question / Objective: We aimed to systematically review the effectiveness and safety of TCM in the treatment of SONFH.

Condition being studied: Osteonecrosis of femoral head (ONFH) is a common refractory disease in orthopedics. Overdose glucocorticoid (GCs) application is a common trigger for ONFH. Traditional Chinese medicine (TCM), as a treatment for osteonecrosis of the femoral head, has been shown to be effective in treating steroid-induced osteonecrosis of femoral head (SONFH). However, a systematic review and meta-analysis of them is lacking. We aimed to systematically review the effectiveness and safety of TCM in the treatment of SONFH.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 July 2021 and was last updated on 06 July 2021 (registration number INPLASY202170015).

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METHODS

Participant or population: The trial will include participants who meet the diagnostic criteria for SONFH. All eligible study participants, regardless of age, race, or sex, will be included in this meta-analysis. Pregnant women, lactating women and patients with other severe diseases will be excluded.

Intervention: Patients in the experimental group should receive TCM treatment alone or in combination with other treatment modalities.

Comparator: Patients in the control group received other non-TCM treatments.

Study designs to be included: The included studies will be all randomized controlled trials (RCTs). There were no restrictions on language or public type.

Eligibility criteria: The trial will include participants who meet the diagnostic criteria for SONFH. All eligible study participants, regardless of age, race, or sex, will be included in this meta-analysis. Pregnant women, lactating women and patients with other severe diseases will be excluded.

Information sources: Electronic databases and other sources including PubMed, Embase, the Cochrane Library, MEDLINE, the Chinese Biomedical Literature Database, China Science and Technology Journal Database, China National Knowledge Infrastructure, and Wanfang Data were searched using computer and manual searches.

Main outcome(s): Overall efficiency, hip pain score (visual analog scale, VAS score)

and hip function (Harris score, WOMAC score, etc.) were the main outcomes.

Quality assessment / Risk of bias analysis: Two investigators based the Cochrane Handbook for systematic reviews 5.3 (<https://www.cochrane.org/>) Recommended assessment tools independently assessed methodological quality. In case of disagreement, this could be resolved by discussion between the two reviewers or with the assistance of a third investigator.

Strategy of data synthesis: We will use RevMan 5.3, provided by the Cochrane Collaboration, for data analysis. We will use the chi-square test and I² statistic to measure heterogeneity between studies. We consider heterogeneity between studies to be low when $P \geq .05$ and $I^2 \leq 50\%$. We will use fixed-effects models for the statistics. When $P < .05$ and $I^2 > 50\%$, we consider the heterogeneity between studies to be high. We will use a random-effects model for the statistics. All data analysis will be conducted with confidence intervals of 95 percent. Continuous data will be analyzed as mean difference or normalized mean difference, whereas dichotomous data will be examined as relative risk. When $P < .05$, it indicates that the difference is statistically significant.

Subgroup analysis: When $P < .05$, it indicates that the difference is statistically significant. If the heterogeneity between studies is high, we will perform subgroup analysis on different herbal medicines to explore whether herbal medicines cause heterogeneity.

Sensitivity analysis: If the heterogeneity between studies is high, we will perform subgroup analysis on different herbal medicines to explore whether herbal medicines cause heterogeneity.

Country(ies) involved: China.

Keywords: traditional Chinese medicine, steroid-induced osteonecrosis of femoral head, protocol, systematic review.

Contributions of each author:

**Author 1 - Peilin He - Conceptualization;
Data curation; Formal analysis;
Methodology; Writing–original draft;
Writing–review & editin.**

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