# INPLASY PROTOCOL

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

Conflicts of interest: None declared.

# Efficacy and safety of traditional Chinese medicine fumigation for the treatment of hip synovitis in children: A protocol for a systematic review and meta-analysis

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**Review question / Objective:** The aim of this protocol is to evaluate the efficacy and safety of TCMF for the treatment of hip synovitis in children.

Condition being studied: Hip synovitis is a common hip disorder in children and a frequent cause of hip or groin pain in children. Its onset is rapid and poses a threat to patient health. Conventional treatment methods have suboptimal efficacy and large side effects. Clinical study surface, the therapeutic effect of traditional Chinese medicine fumigation (TCMF) on hip synovitis in children is obvious, therefore, we aimed to systematically review the efficacy and safety of TCMF on hip synovitis in children.

Information sources: Use computer search and manual search for relevant articles, the retrieved databases included PubMed, Web of Science, EMBASE database, Cochrane Library, MEDLINE, Wanfang Data, Chinese biomedical literature database, China National Knowledge Infrastructure, Chinese science and technology journals database, and World Health Organization International Clinical Trials Registry Platform. All the retrieved literature was established from the database to today. The different retrieval methods were adapted according to different database characteristics.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 September 2021 and was last updated on 05 September 2021 (registration number INPLASY202190010).

## INTRODUCTION

**Review question / Objective:** The aim of this protocol is to evaluate the efficacy and safety of TCMF for the treatment of hip synovitis in children.

Condition being studied: Hip synovitis is a common hip disorder in children and a frequent cause of hip or groin pain in children. Its onset is rapid and poses a threat to patient health. Conventional treatment methods have suboptimal efficacy and large side effects. Clinical study surface, the therapeutic effect of traditional Chinese medicine fumigation (TCMF) on hip synovitis in children is obvious, therefore, we aimed to systematically review the efficacy and safety of TCMF on hip synovitis in children.

### **METHODS**

Participant or population: Participants in this study had to meet the diagnostic criteria for synovitis of the hip in children, which is diagnosed through three areas: physical examination, imaging, and laboratory tests. Gender, age and treatment course were not restricted.

Intervention: Patients in the experimental group should receive conventional TCMF treatment.

**Comparator:** Patients in the control group received conventional treatments: oral nonsteroidal anti-inflammatory drugs, static antibiotics, antiviral drugs, skin traction, surgical treatment, etc.

Study designs to be included: Only randomized controlled trials (RCTs) were used to evaluate the efficacy and safety of TCMF for synovitis of the hip in children.

Eligibility criteria: Only randomized controlled trials (RCTs) were used to evaluate the efficacy and safety of TCMF for synovitis of the hip in children, and case reports, conferences, animal studies, and nonrandomized studies would be excluded without the limitation of publication type, language.

Information sources: Use computer search and manual search for relevant articles, the retrieved databases included PubMed, Web of Science, EMBASE database, Cochrane Library, MEDLINE, Wanfang Data, Chinese biomedical literature database, China National Knowledge Infrastructure, Chinese science and technology journals database, and World Health Organization International Clinical Trials Registry Platform. All the retrieved literature was established from the database to today. The different retrieval methods were adapted according to different database characteristics.

Main outcome(s): The primary outcomes were Harris hip function score and hip ultrasound level.

Quality assessment / Risk of bias analysis: Two investigators independently assessed the methodological quality of each included study according to the Cochrane Handbook for Systematic Reviews 5.3 (https://www.cochrane.org/) as the recommended assessment tool. Any disagreement between investigators was resolved by discussion.

Strategy of data synthesis: We adopted Revman 5.3 software for all statistical analyses. The chi-square test and I2 statistic were used to measure heterogeneity between studies. If any substantial heterogeneity was found (P < 0.05 and I2 > 50%), then we used randomeffects model statistics; otherwise, we used the fixed effects model for statistics. All data analyses were performed with 95% confidence intervals. Continuous data were analyzed as the mean difference or the normalized mean difference, whereas dichotomous data were considered as the relative risk. In cases of P < 0.05, the difference was statistically significant.

Subgroup analysis: If the heterogeneity between studies was high, we would conduct subgroup analysis of heterogeneity.

Sensitivity analysis: We used sensitivity analysis to assess the stability of the results.

Country(ies) involved: China.

Keywords: hip synovitis in children, traditional Chinese medicine fumigation, Efficacy and safety, protocol, systematic review.

#### **Contributions of each author:**

Author 1 - Junming Chen -Conceptualization; Data curation; Formal analysis; Methodology; Writing-original draft; Writing-review & editing.

Author 2 - Peilin He - Data curation; Formal analysis; Methodology; Writing–original draft; Writing–review & editing.

Author 3 - Qianhua Liu - Data curation; Writing-review & editing.

Author 4 - Ning Liu - Data curation; Writing-review & editing.

Author 5 - Youwen Liu - Data curation; Writing-review & editing.

Author 6 - Chen Yue - Conceptualization; Data curation; Formal analysis; Methodology; Project administration; Supervision; Writing-review & editing.