

INPLASY PROTOCOL

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None declared.

Evaluation of efficacy and safety of traditional Chinese medicine in the treatment of hip synovitis in children: A protocol for systematic review and meta-analysis

Chen, J¹; He, P²; Liu, Q³; Liu, N⁴; Liu, Y⁵; Yue, C⁶.

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

Condition being studied: Synovitis of the hip in children is a nonspecific inflammatory change of the hip, with transient acute pain, swelling, and effusion as the main clinical manifestations. With an incidence of approximately 3: 1 in men and women, it is self-limiting and is the most common cause of hip pain in children aged 3–8 years. Its etiology has not been fully determined until now and is generally considered as temporary hip pain and dysfunction. Caused by bacterial or viral infection, hip joint damage, excessive fatigue, allergy, and so on. The disorder is usually acute, with the child complaining of hip pain, limping, or refusal to walk. If the disease is not correctly diagnosed at an early stage, without active treatment, and the course of the disease is prolonged, it not only affects hip function but may even evolve to avascular necrosis of the femoral head, triggering developmental disorders of the hip in children. At present, the clinical drug treatment of the disease is mainly using oral non-steroidal anti-inflammatory drugs, intravenous antibiotics, anti-viral drugs, etc., all have adverse drug reactions and safety problems; Surgical treatment of this disease has certain trauma and risks. Therefore, finding the optimal treatment for synovitis of the hip in children is a difficult task for clinicians.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 October 2021 and was last updated on 22 October 2021 (registration number INPLASY2021100087).

INTRODUCTION

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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 TCM treatment, and subgroup analysis was performed to analyze different TCMs with different treatment durations, while patients in the control group received conventional treatments: oral nonsteroidal anti-inflammatory drugs, static antibiotics, antiviral drugs, skin traction, surgical treatment, etc.

Comparator: Patients in the experimental group should receive conventional TCM treatment, and subgroup analysis was performed to analyze different TCMs with different treatment durations, while 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) will be used to evaluate the efficacy and safety of TCM in the treatment of hip synovitis in children; case reports, conferences, animal studies, and nonrandomized studies will be excluded, with no restrictions on publication type or language.

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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. We briefly described the search process of PubMed.

Main outcome(s): The primary outcomes were Harris hip score(HHS) 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 $I^2 > 50\%$), then we used random-effects 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. Lastly, we used sensitivity analysis to assess the stability of the results. If necessary, funnel plots and egger tests were created and checked to ensure that there was no bias in the publication.

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Country(ies) involved: China.

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

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