

INPLASY PROTOCOL

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The authors have no conflicts of interest to disclose.

Efficacy and safety of pricking-blood therapy for Acute Gouty Arthritis : A protocol for systematic review and meta-analysis

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Review question / Objective: To systematically investigate the efficacy and safety of pricking-blood therapy in treating Acute Gouty Arthritis.

Condition being studied: Gouty arthritis (GA) is a lens-related disease, which is an acute inflammatory reaction caused by the deposition of oversaturated monosodium urate (MSU) in the joints and periarticular tissue. It is usually associated with hyperuricemia caused by purine metabolic disorders and(or) decreased uric acid excretion. Acute Gouty Arthritis (AGA) is characterized by sudden redness, swelling, heat, and pain in the joint and its surrounding soft tissue, usually lasting for several days or weeks and relieves itself. With the disease's progress, the acute attack of GA will be gradually frequent, and the number of joints involved will gradually increase, which will eventually lead to chronic arthritis and joint deformities, which will significantly affect humans' quality of life. Pricking-blood therapy is a kind of External Therapy of Traditional Chinese Medicine(ET-TCM). In China, it is often used in AGA treatment with damp-heat syndrome. Evidence from RCTs has shown that pricking-blood therapy is an effective way to treat AGA. There is still a lack of evidence-based medicine evidence to support it. In this protocol, we aim to evaluate the efficacy and safety of pricking-blood therapy for AGA objectively and provide reliable evidence for the clinical application of pricking-blood therapy in AGA.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 October 2020 and was last updated on 24 October 2020 (registration number INPLASY2020100094).

INTRODUCTION

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METHODS

Search strategy: We will search the following databases from the establishment to December 2020: PubMed, Embase, Web of Science, the Cochrane Library, China National Knowledge Infrastructure, the Chongqing VIP Chinese Science and Technology Periodical Database, Wanfang Database, and China Biomedical Literature Database. We will also manually search Chinese Acupuncture & Moxibustion, Acupuncture Research, Chinese Clinical Trial Register, and unpublished studies or references. The search strategy will be constructed in the form of Medical Subject Heading (MeSH) combine with keywords, including “gout, Gouts, Gouty Arthritis, pricking blood

therapy, pricking, cupping and blood letting therapy, acupuncture and blood-letting”, etc.

Participant or population: Patients who met the standard of AGA diagnosis will be included.

Intervention: The treatment group was treated alone with pricking-blood therapy, or pricking-blood therapy combined with conventional therapy and other adjuvant therapy (Chinese herbal medicine, acupuncture, and moxibustion).

Comparator: The control group was treated with conventional therapy and(or) other adjuvant therapy without pricking-blood therapy.

Study designs to be included: Randomized controlled trials (RCTs) will be included in this review.

Eligibility criteria: The study is considered qualified when the following criteria are met. (1) Type of studies. Randomized controlled trials (RCTs) will be included in this review. (2) Type of participants. Patients who met the standard of AGA diagnosis will be included. (3) Type of interventions. The treatment group was treated alone with pricking-blood therapy, or pricking-blood therapy combined with conventional therapy and other adjuvant therapy (Chinese herbal medicine, acupuncture, and moxibustion). (4) Type of comparators. The control group was treated with conventional therapy and(or) other adjuvant therapy without pricking-blood therapy. (5) Types of outcome measures. The total effective rate and Visual Analogue Scale(VAS) score are the primary outcome indicators of this study. This study's secondary outcome is as follows: inflammatory indicators (such as CRP and ESR), uric acid, and incidence of adverse events.

Information sources: We will search the following databases : PubMed, Embase, Web of Science, the Cochrane Library, China National Knowledge Infrastructure, the Chongqing VIP Chinese Science and

Technology Periodical Database, Wanfang Database, and China Biomedical Literature Database. We will also manually search Chinese Acupuncture & Moxibustion, Acupuncture Research, Chinese Clinical Trial Register, and unpublished studies or references.

Main outcome(s): The total effective rate and Visual Analogue Scale(VAS) score are the primary outcome indicators of this study.

Additional outcome(s): Inflammatory indicators (such as CRP and ESR), uric acid, and incidence of adverse events.

Data management: We will eliminate duplicate studies from the search results by Endnote X9 software. Two reviewers will screen the literature independently. Provided that the two reviewers have different opinions, whether or not the literature should be included, they should resolve it by discussion. The selection will be performed according to the PRISMA flow chart. The data will be screened and extracted by two researchers. The content of the data extraction includes: Author's name, Year of publication, Title, Country, The enforcement time of the study, Study design, Sample size, Participants, Intervention, Comparison, Outcome, and some relevant characteristics.

Quality assessment / Risk of bias analysis: There may be biases in clinical trials from selecting and assigning subjects, implementing interventions, following up matters, and measuring and reporting findings at every stage. Thus, RCTs will be evaluated through the bias risk assessment tool (Cochrane Handbook for Systematic Reviews of Interventions). It includes the following six items: random sequence generation; allocation concealment; blinding of participants, caregivers, outcome assessors; incomplete outcome data; selective outcome reporting; and other bias. According to each study's results, the two researchers made 'low-risk' 'high-risk' or 'unclear risk' assessment of the above six items independently. If the two researchers occur different opinions,

the objection will be decided by the third reviewer.

Strategy of data synthesis: RevMan5.3.5 software will conduct this meta-analysis. A random-effects model will be used to estimate the pooled primary and secondary outcomes. The forest plots will display the results of the meta-analysis. If the products are not suitable for meta-analysis, we will conduct a descriptive analysis. Only when more than 10 RCTs are included can we use funnel charts to assess publication bias. Heterogeneity will be assessed using a Chi-square test and I² statistics (P-value <0.10 or I² over 50% were defined as substantial heterogeneity). The risk ratio (RR) and its 95% confidence intervals (CIs) will be used in the dichotomous variables. Continuous variables will be statistically analyzed using weighted mean difference (WMD) or standardized mean difference(SMD) and its 95% CIs.

Subgroup analysis: If the heterogeneity source cannot be found after sensitivity analysis, we will do further subgroup analysis.

Sensibility analysis: We will use the leave-one-out method for sensitivity analysis to judge the stability of outcome indicators.

Language: English and Chines.

Country(ies) involved: China.

Keywords: pricking-blood therapy, protocol, acute gouty arthritis, systematic review.

Contributions of each author:

Author 1 - Renliang Li - Conceptualization, Data curation, Investigation, Supervision, Writing-original draft, Writing-review & editing.

Author 2 - Ping Zhang - Formal analysis, Methodology, Software, Writing-original draft, Writing-review & editing.

Author 3 - Ziyi Hu - Conceptualization, Investigation, Supervision, Writing - original draft.

Author 4 - Ying Yi - Data curation, Methodology, Writing - original draft.

**Author 5 - Lisha Chen - Data curation,
Software, Writing – review & editing.**
Author 6 - Hengyi Zhang - Formal analysis.
**Author 7 - Hong Li - Methodology,
Software.**
Author 8 - Wanting Liu - Methodology.
Author 9 - Mengwen Wu - Formal analysis.