INPLASY PROTOCOL

To cite: Fan et al. Efficacy and safety of Chinese herbal compound in the treatment of acute gouty arthritis: A protocol of a systematic review and meta-analysis. Inplasy protocol 202240153. doi: 10.37766/inplasy2022.4.0153

Received: 26 April 2022

Published: 26 April 2022

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Support: **None.**

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

Conflicts of interest:
None declared.

Efficacy and safety of Chinese herbal compound in the treatment of acute gouty arthritis: A protocol of a systematic review and meta-analysis

Fan, Y[1]; Zhao, X[2]; He, X[3]; Chen, H[4].

Review question / Objective: **To evaluate the efficacy and safety of Chinese herbal compound in the treatment of acute gouty arthritis.**
Eligibility criteria: **1.1.1 Literature type Randomized controlled trials of treating AGA with Chinese herbal compound alone, whether blind or not, was limited to Chinese literature and English literature.1.1.2 SubjectsThe time of onset, gender, and age of patients diagnosed with acute gouty arthritis were not restricted.1.1.3 Intervention measures The treatment group was treated with traditional Chinese medicine compound, which could be proprietary Chinese medicine, self-made prescription or classic prescription, and the dosage form could be traditional decoction, granule or pill, while the control group was treated with non-steroidal anti-inflammatory painkillers, and the frequency, dosage and course of use were not limited.1.1.4 Outcome indicators(1) Main outcome measures: total response rate; (2) Secondary outcome indicators: visual analog scale (VAS), TCM syndrome score, blood uric acid, ESR, CRP, and incidence of adverse reactions.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 April 2022 and was last updated on 26 April 2022 (registration number INPLASY202240153).

INTRODUCTION

Review question / Objective: **To evaluate the efficacy and safety of Chinese herbal compound in the treatment of acute gouty arthritis.**

Condition being studied: **The research group published several papers on meta-analysis.**

METHODS

Search strategy: 1 PubMed
Number Search terms
#1 Gout [MeSH]
#2 Gouts [Title/Abstract]
#3 Gouty [Title/Abstract]
#4 #1 OR #2 OR #3
#5 Traditional Chinese medicine [Title/Abstract]
#6 Chinese herbal medicine [Title/Abstract]
#7 TCM [Title/Abstract]
#8 #5 OR #6 OR #7
#9 #4 AND #8.

Participant or population: The time of onset, gender, and age of patients diagnosed with acute gouty arthritis were not restricted.

Intervention: The treatment group was treated with traditional Chinese medicine compound, which could be proprietary Chinese medicine, self-made prescription or classic prescription, and the dosage form could be traditional decoction, granule or pill, while the control group was treated with non-steroidal anti-inflammatory painkillers, and the frequency, dosage and course of use were not limited.

Comparator: (1) Main outcome measures: total response rate; (2) Secondary outcome indicators: pain visual analog score, TCM syndrome score, serum uric acid, ESR, CRP, incidence of adverse reactions.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: 1.1.1 Literature type Randomized controlled trials of treating AGA with Chinese herbal compound alone, whether blind or not, was limited to Chinese literature and English literature.1.1.2 SubjectsThe time of onset, gender, and age of patients diagnosed with acute gouty arthritis were not restricted.1.1.3 Intervention measuresThe treatment group was treated with traditional Chinese medicine compound, which could be proprietary Chinese medicine, self-made prescription or classic prescription, and the dosage form could be traditional decoction, granule or pill, while the control group was treated with non-steroidal anti-inflammatory painkillers, and the frequency, dosage and course of use were not limited.1.1.4 Outcome indicators(1) Main outcome measures: total response rate; (2) Secondary outcome indicators: visual analog scale (VAS), TCM syndrome score, blood uric acid, ESR, CRP, and incidence of adverse reactions.

Information sources: CNKI, Wanfang Database, VIP, Chinese Biomedical Database, PubMed, The Cochrane Library, EMBASE, Web of Science.

Main outcome(s): Total effective rate.

Additional outcome(s): (2) Secondary outcome indicators: pain visual analog score, TCM syndrome score, serum uric acid, ESR, CRP, incidence of adverse reactions.

Quality assessment / Risk of bias analysis: The assessment of risk of bias will be carried out independently by two reviewers via the Cochrane Collaboration's "Risk of bias" tool. According to these criteria (random sequence generation, allocation concealment, blinding, incomplete data, selective result reports and other bias), study bias is classified into the following levels: unclear, low rand high risk. If the assessment of bias causes controversy, it will be necessary to discuss it with the third reviewer.

Strategy of data synthesis: Statistical analysis is performed by a 95% CIs. Odds ratio (OR) and relative risk (RR) are usually applied to dichotomy result data. For continuous results, if the measurement method and measurement unit are the same, the weighted mean difference (WMD) shall be used; if the measurement method or measurement unit is different, the standard mean difference (SMD) shall be used for statistical analysis.

Subgroup analysis: In order to better verify our research objectives, this study divided them into three subgroups for analysis

according to the different treatment duration of the included studies: short-term (7 d), medium-term (14-15 d) and long-term (30 d).

Sensitivity analysis: **Sensitivity analysis will be applied to test the robustness of key decisions made during the review process. The sensitivity analysis of all indicators is carried out through one-to-one elimination method to verify the stability of the obtained results by Rev Man V.5.3.5.**

Country(ies) involved: **China.**

Keywords: **Acute gouty arthritis; Chinese medicine compound; Randomized control; Systematic review; Meta analysis.**

Contributions of each author:

Author 1 - Yihua Fan - The author conceived the review protocol and drafted the manuscript.
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