

# INPLASY PROTOCOL

To cite: Wang et al. Chinese herbal medicine Si-Miao-San Decoction for Acute Gouty Arthritis: A protocol for systematic review and meta-analysis of randomized controlled trials. Inplasy protocol 202040163. doi: 10.37766/inplasy2020.4.0163

Received: 23 April 2020

Published: 23 April 2020

**Corresponding author:**  
heting wang

916960297@qq.com

**Author Affiliation:**  
Hospital of Chengdu  
University of Traditional  
Chinese Medicine

**Support:** None.

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

**Conflicts of interest:** None.

## Chinese herbal medicine Si-Miao-San Decoction for Acute Gouty Arthritis: A protocol for systematic review and meta-analysis of randomized controlled trials

Wang, H<sup>1</sup>; Chen, S<sup>2</sup>; Luo, Y<sup>3</sup>; Liu, Q<sup>4</sup>; Zhang, Y<sup>5</sup>; Zhang, X<sup>6</sup>.

**Review question / Objective:** Is chinese herbal medicine Si-Miao-San Decoction beneficial for Acute Gouty Arthritis?

**Condition being studied:** Gouty arthritis, one of the most common forms of inflammatory arthritis, is characterized by hyperuricemia and deposition of monosodium urate and greatly lowers health-related quality of life and places a significant economic burden on the healthcare costs. Global epidemiology of gout indicated that the distribution of gout was uneven across the world, with prevalence being highest in Pacific countries. Developed countries incline to have a higher load of gout than developing countries, and the prevalence and incidence seem to be increasing. Goal of treatment in an acute gout attack is to reduce the serum urate level and treatment is continued until the flare has resolved. Non-steroidal anti-inflammatory drugs and colchicines are the most popular treatments for acute attacks in European countries. But the potential gastrointestinal and cardiovascular risks from these drugs and the risk factors for recurrent attacks due to drug discontinuation are well documented. Simiao pill, derived from Ermiao powder, and described in a famous traditional Chinese medicine monograph Chengfang Biandu in Qing Dynasty of China, was widely applied for treatment of gouty arthritis.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 April 2020 and was last updated on 23 April 2020 (registration number INPLASY202040163).

### INTRODUCTION

**Review question / Objective:** Is chinese herbal medicine Si-Miao-San Decoction beneficial for Acute Gouty Arthritis?

**Condition being studied:** Gouty arthritis, one of the most common forms of inflammatory arthritis, is characterized by hyperuricemia and deposition of monosodium urate and greatly lowers

health-related quality of life and places a significant economic burden on the healthcare costs. Global epidemiology of gout indicated that the distribution of gout was uneven across the world, with prevalence being highest in Pacific countries. Developed countries incline to have a higher load of gout than developing countries, and the prevalence and incidence seem to be increasing. The goal of treatment in an acute gout attack is to reduce the serum urate level and treatment is continued until the flare has resolved. Non-steroidal anti-inflammatory drugs and colchicines are the most popular treatments for acute attacks in European countries. But the potential gastrointestinal and cardiovascular risks from these drugs and the risk factors for recurrent attacks due to drug discontinuation are well documented. Simiao pill, derived from Ermiao powder, and described in a famous traditional Chinese medicine monograph Chengfang Biandu in Qing Dynasty of China, was widely applied for treatment of gouty arthritis.

## METHODS

**Search strategy:** Relevant literature was retrieved using multiple online databases including PubMed, Web of Science, Embase, the Cochrane Library, the Chinese National Knowledge Infrastructure Database (CNKI), Wangfang and the VIP database. There is no restriction on study date or publication language, type and status. The keywords used in these searches were: "Acute Gouty Arthritis", "Si-Miao-San Decoction", "Si-Miao-San", "Chinese herbal medicine", "modified Simiao decoctions", "Simiao pill", search strategies were used for the Chinese and foreign language databases. In addition, the reference lists of previously published systematic reviews on the subject of Si-Miao-San for the treatment of AGA were manually examined for pertinent studies.

**Participant or population:** All adult patients (18 years and older, no upper age limit) with a diagnosis of acute gouty arthritis will be considered for this review. We will consider the American College of Rheumatology

(ACR) preliminary criteria for the classification of gout, or monosodium urate (MSU) crystal diagnosis, or both diagnostic criteria.

**Intervention:** Chinese herbal medicine Si-Miao-San Decoction for Acute Gouty Arthritis. In Chinese medicine, gouty arthritis is correlated with dampness, heat, sputum, and stasis. Among numerous effective prescriptions, Simiao pill, derived from Ermiao powder, and described in a famous traditional Chinese medicine monograph Chengfang Biandu in Qing Dynasty of China, was widely applied for treatment of gouty arthritis. It is composed of four individual herbs: Rhizoma Atractylodis, Cortex Phellodendri, Radix Achyranthis Bidentatae, and Semen Coicis. Some new research has shown that the Simiao pill and its derivative prescriptions showed their beneficial efficacy in treating gouty arthritis and hyperuricemia in vitro and in vivo.

**Comparator:** No current/recent Si-Miao-San Decoction use.

**Study designs to be included:** Randomized controlled trials (RCTs).

**Eligibility criteria:** All adult patients (18 years and older, no upper age limit) with a diagnosis of acute gouty arthritis will be considered for this review. We will consider the American College of Rheumatology (ACR) preliminary criteria for the classification of gout, or monosodium urate (MSU) crystal diagnosis, or both diagnostic criteria.

**Information sources:** PubMed, web of science, EMBASE, the Cochrane Library, the Chinese National Knowledge Infrastructure Database (CNKI), Wangfang and the VIP database.

**Main outcome(s):** Clinical efficacy 1. Pain control by visual analog scale, numeric rating scale, or queries about time to first evidence of meaningful relief and average time to complete relief; 2. Function of the target joint assessed by numeric rating scale; 3. Joint swelling assessment.

---

**Quality assessment / Risk of bias analysis:**

The Cochrane risk of bias tool will be used to assess the risk of bias in Randomised Controlled Trials (<https://methods.cochrane.org/bias/resources/rob-2-revised-cochrane-risk-bias-tool-randomized-trials>), and the ROBINS-I tool (Risk Of Bias In Non-randomized Studies - of Interventions: <http://www.riskofbias.info/welcome/home>) for non-randomised studies. Assessments will be carried out by two reviewers independently, with discrepancies discussed with a third reviewer to reach a consensus. Sensitivity analyses will be conducted to assess how excluding studies at high risk of bias influences the findings.

**Strategy of data synthesis:** For each study effect estimates and 95% confidence intervals will be calculated using intention-to-treat principles. Statistical heterogeneity will be assessed using the Cochran  $Q^2$  test ( $Q^2$ test), with the  $I^2$  statistic used to assess the percentage of variability between studies that is due to heterogeneity rather than to sampling error. Meta-analysis will be used to pool the effect estimates, using fixed-effect or random-effects methods (depending on heterogeneity). Meta-regression will be used to assess the study-level factors contributing to heterogeneity across studies.

**Subgroup analysis:** If the necessary data are available, subgroup analyses will be conducted for with different comparators separately.

**Sensibility analysis:** Sensitivity analysis is mainly used to evaluate the robustness of the primary outcome measures. The method is that removing the low-level quality study one by one and then merge the data to assess the impact of sample size, study quality, statistical method, and missing data on results of meta analysis.

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

**Keywords:** Acute Gouty Arthritis, Si-Miao-San Decoction, chinese herbal medicine, Systematic review.

**Contributions of each author:**

Author 1 - heting wang - Conceptualization, Resources, Software, Writing-original draft.

Author 2 - shiyin chen - Data curation, Project administration, Supervision, Writing-original draft.

Author 3 - yong luo - Data curation, Formal analysis, Supervision.

Author 4 - qingsong liu - Formal analysis, Resources, Software, Supervision.

Author 5 - yuan zhang - Methodology.

Author 6 - xiyu zhang - Conceptualization, Funding acquisition, Project administration, Writing-eview & editing.