INPLASY PROTOCOL

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Corresponding author:
Mengjun Pu

774260426@qq.com

Author Affiliation:
Department of geriatrics of the Affiliated Hospital, North Sichuan Medical College

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Conflicts of interest:
The authors have no conflicts of interest to disclose.

Traditional chinese medicine for gouty arthritis: a protocol for meta-analysis

Pu, MJ[1]; Yao, CJ[2].

Review question / Objective: **The aim of this meta-analysis of randomized controlled trails is to evaluate the efficacy between different traditional chinese medicine for gouty arthritis.**
Condition being studied: **Gouty arthritis is due to increased uric acid, uric acid salt deposited in the joint, causing joint swelling and heat pain.The etiology of GA is not completely clear. Multiple studies have found that genetic susceptibility, immune imbalance, intestinal flora, neuroendocrine and environmental factors are intertwined and related to each other, and all participate in the pathogenesis in varying degrees . Therefore, GA is considered to be a multifactor complex disease with genetic tendency. Lucky, acupuncture and Chinese medicine have better therapeutic effect on GA.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 November 2020 and was last updated on 08 November 2020 (registration number INPLASY2020110028).

INTRODUCTION

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and related to each other, and all participate in the pathogenesis in varying degrees . Therefore, GA is considered to be a multifactor complex disease with genetic tendency. Lucky, acupuncture and Chinese medicine have better therapeutic effect on GA.

METHODS

Participant or population: Patients who are diagnosed with RA according to ACR(1997)will be included in the analysis, regardless of their age, gender, ethnicity, or background.

Intervention: The intervention measures of the experimental group were only TCM, such as Chinese herbal medicine, Chinese patent medicine, acupuncture, moxibustion, massage, and so on. It can be mono therapy or combination. RCT comparing the above 2 therapies can also be included, and those who combine Western medicine will be excluded.

Comparator: The control group received conventional treatment of Western medicine, including the use of Febuxostat, Colchicine or a combination of both.

Study designs to be included: Randomized controlled trails will be included.

Eligibility criteria: Two authors independently complete the following process: according to the above search strategy to complete the process of document retrieval, import documents into EndNote X7 for centralized management. Then, according to the inclusion and exclusion criteria, filter the literature by reading the title and abstract. If it is not possible to determine whether the article meets the requirements based on the inclusion and exclusion criteria, then read the full text to select. In the entire literature screening process, if the 2 authors have different opinions, the third author joins the discussion to get a common opinion.

Information sources: The China National Knowledge Infrastructure, Wanfang Database , Chinese Science and Technology Periodical Database, Chinese Biomedical Literature Database, Pubmed, Embase, Web of Science, and the Cochrane library.

Main outcome(s): The main outcome include effectiveness, basic recovery, marked effect, improvement; remission rate , relapse rate, clinical absolute score, and relative score.

Additional outcome(s): Secondary outcome measures: including any related adverse reactions, serum uric acid concentration.

Quality assessment / Risk of bias analysis: The 2 authors will independently assess the risk of bias of the included studies based on the bias risk aasessment tool recommended in the Cochrane “Risk of bias” assessment tool. Including 7 items: random sequence generation, allocation concealment, blind participants and personnel, blind assessment of results, incomplete result data, selective reports, and other biases. The results in each field will be divided into 3 levels: low bias risk, high bias risk, and unclear bias risk. The 2 authors will exchange assessment results and check whether the assessment results are consistent. If there is a disagreement, the third author will participate in the discussion and determine the final result.

Strategy of data synthesis: When meta-analysis is available, RevManV5.3 will be applied to analyze data. Data will use a random effects model with 95% CIs as substantial heterogeneity is expected among included studies. If the I2 test is >75%, we will not perform meta-analysis if the heterogeneity cannot ascertain possible causes from both clinical and methodological diversity. The fixed-effects model will be utilized for data synthesis if the I2 is <50%, while the random-effects model will be performed for data synthesis when the I2 is in the range of 50% to 75%.

Subgroup analysis: If the Chi-squared test and Higgins I2 test detect obvious heterogeneity between studies, we will conduct a subgroup analysis from the following aspects: different types of TCM,

treatment time, clinic classification, course of disease, and so on.

Sensibility analysis: **In order to ensure the Credibility of the research results, we will conduct a sensitivity analysis of the included literature and will eliminate low-quality literature.**

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

Keywords: **Gouty arthritis, meta-analysis, protocol, traditional Chinese medicine.**

Contributions of each author:

Author 1 - Mengjun Pu - The author drafted the manuscript.
Email: **774260426@qq.com**
Author 2 - Chengjiao Yao - The author provided statistical expertise.
Email: **14807219@qq.com**