INPLASY PROTOCOL

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Conflicts of interest:
None.

Safety and efficacy of acupuncture combined with herbal medicine for Gouty arthritis: protocol for a systematic review

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Review question / Objective: **P: Patients with gouty arthritis; I: acupuncture combined with herbal medicine for Gouty arthritis; C: acupuncture combined with herbal medicine versus no treatment; acupuncture combined with herbal medicine versus herbal medicine alone; acupuncture combined with herbal medicine versus acupuncture alone; acupuncture combined with herbal medicine versus Other therapy; O: acupuncture combined with herbal medicine could reduce inflammatory factors expression, improve the clinical symptom and relieve pain, while having fewer side effects and a relatively lower cost compared to Western medicine. S: Randomized controlled trial.**
Condition being studied: **Gouty arthritis is a common and complex refractory disease, which is the most common inflammatory arthritis in developed countries. It is characterized by tissue damage caused by the bodies purine metabolism disorder and the increase of blood uric.patients with gouty arthritis have a low quality of life.and the characteristics of disease changes can affect the psychological and mental health of patients.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 September 2020 and was last updated on 02 September 2020 (registration number INPLASY202090006).

INTRODUCTION

Review question / Objective: **P: Patients with gouty arthritis; I: acupuncture combined with herbal medicine for Gouty arthritis; C: acupuncture combined with herbal medicine versus no treatment; acupuncture combined with herbal medicine versus herbal medicine alone; acupuncture combined with herbal medicine versus acupuncture alone; acupuncture combined with herbal**

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medicine versus Other therapy; O: acupuncture combined with herbal medicine could reduce inflammatory factors expression, improve the clinical symptom and relieve pain, while having fewer side effects and a relatively lower cost compared to Western medicine. S: Randomized controlled trial.

Condition being studied: Gouty arthritis is a common and complex refractory disease, which is the most common inflammatory arthritis in developed countries. It is characterized by tissue damage caused by the bodies purine metabolism disorder and the increase of blood uric. Patients with gouty arthritis have a low quality of life.and the characteristics of disease changes can affect the psychological and mental health of patients.

METHODS

Search strategy: We will electronically search the randomized controlled trials in the following databases: including the Chinese Biomedical Literature Database (CBM), MEDLINE, PubMed, the Cochrane Library, Excerpta Medica (EMBASE), the China National Knowledge Infrastructure Database (CNKI), the Wanfang database and the Chinese Scientific Journal Database (VIP database) will be searched from their inception to 1 June 2021.

Participant or population: Regardless of the subtype of gouty arthritis, all participants who have been diagnosed as having gouty arthritis will be focused on. There will be no restrictions on age, ethnicity, sex, economic status and education background.

Intervention: Experimental interventions Acupuncture is defined as irritation of acupoints by needles. Regardless of the duration and frequency of acupuncture combined with herbal medicine in the treatment of gouty arthritis, All trials that evaluating acupuncture (auricular acupuncture or catgut embedding or body acupuncture and others acupuncture therapy) combined with herbal medicine (decoction of TCM, granules, chinese patent medicine and other Dosage Forms of herbal medicine) for gouty arthritis will be included. Their possible prognostic effects after the intervention will be assessed.

Comparator: If the patients with gouty arthritis in the control group were treated with acupuncture or herbal medicine, the studies will be picked.

Study designs to be included: ALL RCTs will be contained, while quasi randomized controlled trials, reviews, animal studies, case reports and randomized crossover studies will be excluded. If these studies include sufficient detail to make a critical evaluation, the abstracts and papers will also be included.

Eligibility criteria: Regardless of the subtype of gouty arthritis, all participants who have been diagnosed as having gouty arthritis will be focused on. There will be no restrictions on age, ethnicity, sex, economic status and education background.

Information sources: We will electronically search the randomized controlled trials in the following databases: including the Chinese Biomedical Literature Database (CBM), MEDLINE, PubMed, the Cochrane Library, Excerpta Medica (EMBASE), the China National Knowledge Infrastructure Database (CNKI), the Wanfang database and the Chinese Scientific Journal Database (VIP database) will be searched from their inception to 1 June 2021. We will also try to search manually for other sources, including clinical trials registration (such as the Chinese Clinical Trial Registration and the Meta Register of Controlled Trials, conference agenda, potential grey literature, present systematic reviews and the reference lists of established publications.

Main outcome(s): Changes in disease state are assessed by physical signs (such as the measurement of gouty arthritis pain and

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severity index) or any available tool will be evaluated as the primary outcome.

Quality assessment / Risk of bias analysis: Based on the Cochrane Handbook for systematic Reviews of interventions, the risk of bias in all studies will be assessed by 2 authors independently using the Cochrane risk of bias assessment tool. Six areas of each trial will be evaluated: generation of random sequences, allocation concealment, blinding method, incomplete outcome data, selective reporting and other bias. Each domain will be divided into three levels of bias: unclear risk, high risk and low risk and "Risk of bias" will be filled in. And any differences will be resolved through negotiation or consulting with other reviewers.

Strategy of data synthesis: Based on the Cochrane Handbook for systematic Reviews of interventions, the risk of bias in all studies will be assessed by 2 authors independently using the Cochrane risk of bias assessment tool. Six areas of each trial will be evaluated: generation of random sequences, allocation concealment, blinding method, incomplete outcome data, selective reporting and other bias. Each domain will be divided into three levels of bias:unclear risk, high risk and low risk and "Risk of bias" will be filled in. And any differences will be resolved through negotiation or consulting with other reviewers.

Subgroup analysis: In order to explore the possible causes of heterogeneity, we will conduct subgroup analysis if there are a sufficient number of studies (at least 10 trials). In addition, if we do not observe the predicted effect in all the subjects, the subgroup analysis can help us find out whether the treatment is effective in some subgroups. The effect of different types of acupuncture combined with herbal Medicine and gouty arthritis will be included for analysis. Similarly, we will also delete studies with medium and/or low quality to ensure the robustness of the results.

Sensibility analysis: In order to assure the robustness of our results, We will conduct sensitivity analysis to eliminate the impact of low-quality studies, with the premise of significant heterogeneity still exists right after validation of inputted data and subgroup analysis. We will contrast the results of these two meta-analyses and decide whether to exclude low-quality researches based on impact on pooled effective size, sample size and strength of evidence. Nevertheless, if all included studies are at high risk of bias, we will not conduct sensitivity analysis.

Country(ies) involved: China.

Keywords: acupuncture; herbal medicine; gouty arthritis; protocol.

Contributions of each author:
Author 1 - Liang Huan - HL drafted the manuscript.
Author 2 - Huang FaSen - FH and HL worked out the search strategy.
Author 3 - Xie Kunming - KX will independently screen the potential researches, carry out data extraction, evaluate the risk of bias, input data into RevMan And complete data synthesis.
Author 4 - Chen Zhaojun - ZC is the guarantor of the article.

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