

INPLASY PROTOCOL

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None declared.

Meta-analysis of the effect of oral administration and external application of traditional Chinese medicine on reducing blood uric acid level in patients with gout

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Review question / Objective: As there are few comprehensive analyses on the effect of internal and external application of Chinese herbal medicine in reducing blood uric acid levels in gout patients, this study aims to investigate the safety and efficacy of internal and external application of Chinese herbal medicine in the treatment of gout (reducing blood uric acid levels in gout patients) by combining effect sizes of several independent randomised clinical control studies using Meta-analysis, to provide a level of evidence-based medical evidence for the treatment and research of gouty arthritis. To evaluate the efficacy and safety of 'internal and external application of Chinese medicine' compared with western medicine in treating gouty arthritis.

Condition being studied: From the perspective of published literature, there are many case studies in China on the topic of "whether the efficacy and safety of internal and external application of Chinese medicine in the treatment of gout are better than that of conventional treatment with western medicine".

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 September 2021 and was last updated on 23 September 2021 (registration number INPLASY202190074).

INTRODUCTION

Review question / Objective: As there are few comprehensive analyses on the effect of internal and external application of Chinese herbal medicine in reducing blood

uric acid levels in gout patients, this study aims to investigate the safety and efficacy of internal and external application of Chinese herbal medicine in the treatment of gout (reducing blood uric acid levels in gout patients) by combining effect sizes of

several independent randomised clinical control studies using Meta-analysis, to provide a level of evidence-based medical evidence for the treatment and research of gouty arthritis. To evaluate the efficacy and safety of 'internal and external application of Chinese medicine' compared with western medicine in treating gouty arthritis.

Rationale: The existing randomised controlled trial of the internal and external application of Chinese herbal medicine for the treatment of gouty arthritis versus conventional western medicine was conducted to compare the efficacy and safety of the internal and external application of Chinese herbal medicine for the treatment of gout with the conventional use of western medicine in reducing blood uric acid levels in patients with gout and to provide objective and definitive clinical evidence.

Condition being studied: From the perspective of published literature, there are many case studies in China on the topic of "whether the efficacy and safety of internal and external application of Chinese medicine in the treatment of gout are better than that of conventional treatment with western medicine".

METHODS

Search strategy: 1. Chinese search formula: TI='痛风'+ '痹症'+ '高尿酸血症'+ '白虎历节'+ '历节' and TI='临床观察'+ '疗效观察'+ '对照' not TI='动物'+ '大鼠'+ '小鼠'+ '体外'+ '针灸'+ '针刺'+ '手法'+ '正骨'+ '电针'+ '脉冲'+ '放血'+ '刺血'+ '刺法'+ '刮痧'+ '足浴'+ '藏药'+ '蒙药'+ '苗药'+ '壮药'+ '藏医'+ '蒙医'+ '苗医'+ '壮医' | K= (痛风AND加味四妙散) OR K= (痛风AND四妙散加味) OR K= (痹症AND加味四妙散) OR K= (痹症AND四妙散加味) OR K= (高尿酸血症AND加味四妙散) OR K= (高尿酸血症AND四妙散加味) OR K= (白虎历节AND方剂) OR K= (历节AND加味四妙散) OR K= (历节AND四妙散加味)) AND T=临床观察OR队列研究OR疗效观察OR对照 | 2.English search formula: Medline: ((gout[MeSH Terms]) OR

podagra[MeSH Terms]) OR arthritis[MeSH Terms]) AND ("Plants, Medicinal"[Mesh]) AND "Chinese medicine"[AB]) AND ("Clinical Trial" [PT]).

Participant or population: Patients with gouty arthritis are used as study subjects and the text mentions that the patients meet the published diagnostic criteria for gouty arthritis, such as the Guidelines for Clinical Research on New Chinese Medicines, the Diagnostic Efficacy Criteria for Chinese Medical Evidence, and the American College of Rheumatology Diagnostic Criteria for Gouty Arthritis.

Intervention: Treatment of gouty arthritis by internal and external application of Chinese herbal medicine (and internal treatment combined with external application of Chinese herbal medicine), with no restriction on the type of Chinese herbal formula or external application of Chinese herbal medicine.

Comparator: The use of Western medicine alone for the treatment of gouty arthritis is unlimited in terms of the mode of administration, dosage, regimen and duration of treatment.

Study designs to be included: A clinical randomised controlled trial of the treatment of gouty arthritis by internal and external application of Chinese herbs. Blinding, age, gender and duration of disease are not limited. Languages are Chinese and English.

Eligibility criteria: Diagnostic criteria, such as the Guidelines for Clinical Research on New Chinese Medicines, the Diagnostic Efficacy Criteria for Chinese Medical Evidence, and the American College of Rheumatology Diagnostic Criteria for Gouty Arthritis.

Information sources: Published randomised controlled trials from China Knowledge Network (CNKI), Researchers searched Wanfang Data, PubMed, and The Cochrane Library self-built to 31 August 2021.

Main outcome(s): Total effective rate, blood uric acid and adverse effects with complete outcome indicators. Total efficiency and blood uric acid index.

Quality assessment / Risk of bias analysis: Publication bias is analysed using an inverted funnel plot. If the graph is symmetrical, there is no publication bias; if not, there is a publication bias.

Strategy of data synthesis: A meta-analysis of crucial outcome indicators was performed using Revman (version 5.3). Count statistics were expressed as relative risk ratio (RR) with 95% confidence interval (95% CI). Measures were expressed as standardised mean difference (SMD) with 95% confidence interval. Heterogeneity was tested for the included data, and, following previous methods, heterogeneity was considered low for I² 50%. Following the previous experience, we will choose the fixed effect model to study the case of medium and low heterogeneity; and the random-effects model to review the case of high heterogeneity.

Subgroup analysis: Methods such as subgroup analysis were attempted when the heterogeneity was too significant. The results were output as forest plots, with publication bias analysed using inverted funnel plots.

Sensitivity analysis: Sensitivity analysis was attempted when the heterogeneity was too significant.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: Chinese medicine; internal and external application; blood uric acid; gouty arthritis; Meta-analysis.

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