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The efficacy and safety of the method of eliminating dampness and removing dampness in the treatment of gouty arthritis: a systematic review and Meta analysis based on randomized controlled trials

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ADMINISTRATIVE INFORMATION

Support - National Science Foundation of China(82104710).

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202590099

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 September 2025 and was last updated on 24 September 2025.

INTRODUCTION

Review question / Objective The purpose of this study is to comprehensively evaluate the efficacy and safety of the method of eliminating dampness and removing dampness in the treatment of gouty arthritis.

Condition being studied Gouty Arthritis (GA) is an inflammatory joint disease caused by the deposition of monosodium urate (MSU) crystals in joints and surrounding tissues. Characterized by sudden severe pain, redness, swelling, and restricted joint movement, it may progress to joint destruction and deformity in severe cases . Epidemiological studies indicate that the prevalence of gout ranges between 0.05% and 0.1%, with male patients generally accounting for a higher proportion than females.

METHODS

Participant or population Acute or chronic gouty arthritis with a clear diagnosis, age ≥ 18 years.

Intervention Intervention with a compound Chinese medicine with spleen strengthening and dampness removal effect on the basis of control group.

Comparator Conventional treatment with western medicine.

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

Eligibility criteria Diagnostic Criteria (Must meet at least one): Western Medical Standards: The 2015 American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR) Gout Classification Criteria, or the 2018 EULAR Evidence-Based Guidelines for Gout Diagnosis ; Traditional Chinese Medicine Standards: Clinical manifestations of gouty arthritis must align with the diagnostic criteria established by the Endocrinology Branch of the Chinese Medical Association.

Information sources China National Knowledge Infrastructure (CNKI), Wanfang Data Resource System, Chinese Journal Database (VIP), China Biomedical Literature Service System (CBM), as well as PubMed, Web of Science, Cochrane Library and EMBASE databases.

Main outcome(s) Total effective rate, Sursem Urine Acid (SUA).

Additional outcome(s) Erythrocyte Sedimentation Rate (ESR), C-reactive protein (CRP), Visual Analogue Scale (VAS).

Quality assessment / Risk of bias analysis Two researchers independently evaluated the quality of included studies using the Cochrane Risk of Bias Assessment Tool (RoB 2.0), assessing aspects such as randomization, concealment of assignments, blinding, completeness of endpoints and data, and selective reporting. Each assessment was classified into three risk levels: low, high, or uncertain. The evaluation process followed a back-to-back independent protocol, with disagreements resolved through consultation or arbitration by third-party evidence-based medicine experts. Final results were presented as risk level distribution charts generated using RevMan 5.4 software.

Strategy of data synthesis For continuous variables such as SUA, ESR, CRP, and VAS scores, effect sizes are calculated using mean differences. For binary variables like clinical response rates, relative risk is employed. In heterogeneity testing, the Q-test and I^2 method are applied. When studies demonstrate good homogeneity ($P > 0.1$ and $I^2 < 50\%$), a fixed-effects model is used; otherwise, a random-effects model is adopted. Sensitivity analysis and subgroup analysis help identify sources of heterogeneity, while funnel plots are utilized to assess publication bias.

Subgroup analysis According to the different intervention time, the group was divided into two subgroups: less than or equal to 4 weeks and more than 4 weeks for analysis.

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.5.4.

Country(ies) involved China.

Keywords Gouty arthritis; Spleen strengthening method; Clinical efficacy; Randomized controlled trial; Meta analysis.

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