Review question / Objective: To assess the comparative efficacy of bloodletting therapy and western medicine for patients with acute gout.

Condition being studied: Gout is a metabolic disease caused by disorder of purine metabolism and/or reduction of uric acid excretion. The deposition of monosodium urate microcrystals in the articular and periarticular tissues elicits acute or chronic inflammatory responses that are known as gouty arthritis. Acute gouty arthritis most frequently begins with the involvement of a single joint in the lower limbs, especially the first metatarsophalangeal joint. The management of acute gouty arthritis includes rapid treatment of acute flares and effective long-term therapy. The first-line drugs of rapid treatment for acute gouty arthritis are dexamethasone, colchicine, nonsteroidal anti-inflammatory drugs (NSAIDs). However, above western medicine have high risk for acquiring severe side effects in cardiovascular and gastrointestinal systems. Therefore, taking a view on alternative medicine has become another popular way for better compliance. Amounts of clinical randomized controlled trials have showed that bloodletting therapy is effective in treating acute gouty arthritis with less adverse events.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 July 2020 and was last updated on 24 July 2020 (registration number INPLASY202070062).
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METHODS

Search strategy: Database: Chinese Database: China Biology Medicine, China National Knowledge Infrastructure (CNKI), Wanfang Data, VIP database; English Database: Pubmed, Cochrane Library, EMBase. Search Strategy and Search Terms: Chinese: Acute gouty arthritis, bloodletting, randomized controlled trials; English: A. Search strategy to locate ‘Arthritis, Gouty’ #1 “Arthritis, Gouty”[MeSH] #2 “Gouty Arthritis” #3 “Arthritides, Gouty” #4 “Gouty Arthritis” #5 #1 OR #2 OR #3 OR #4 B. Search strategy to locate ‘Bloodletting’ #6 “Bloodletting”[MeSH] C. Search strategy to locate RCTs #7 “Randomized Controlled Trial as Topic”[MeSH] #8 “Clinical Trials, Randomized” #9 “Trials, Randomized Clinical” #10 “Controlled Clinical Trials, Randomized” #11 #7 OR #8 OR #9 OR #10 D. Search strategy to locate studies for this review #5 AND #6 AND #11.

Participant or population: Adult patients (age ≥ 18 years) with a diagnosis of acute gouty arthritis.

Intervention: Bloodletting therapy.

Comparator: Western medicine.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: Randomized controlled trials that compared bloodletting therapy and western medicine for patients with acute g.

Information sources: Chinese Database: China Biology Medicine, China National Knowledge Infrastructure (CNKI), Wanfang Data, VIP database; English Database: Pubmed, Cochrane Library, EMBase.

Main outcome(s): Primary outcome: Pain assessed by visual analog scale (VAS).

Additional outcome(s): Secondary outcome: (1) Total effective rate; (2) uric acid; (3) erythrocyte sedimentation rate (ESR); (4) serum C-reactive protein level.

Quality assessment / Risk of bias analysis: Two authors assessed the risk of bias of the included studies using the methods recommended by the Cochrane Collaboration for the following terms. Six domains should be scored: sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting and other sources of bias. The risk of bias was graded as low, high and unclear.

Strategy of data synthesis: Traditional meta-analysis were conducted for studies that directly compared bloodletting therapy and western medicine. Odds ratios (OR) and standardized mean difference (SMD) with corresponding 95% confidence intervals (CIs) were used for dichotomous and continuous outcomes, respectively.

Subgroup analysis: Comparative efficacy of bloodletting therapy and western medicine.

Sensibility analysis: In order to check the stability of the result, sensitivity analysis was performed by sequential delete single study if suitable.

Country(ies) involved: China.
**Keywords:** Acute gouty arthritis, bloodletting therapy, western medicine, efficacy.

**Contributions of each author:**
Author 1 - Sihui Li - Author 1 drafted the manuscript.
Author 2 - Weishang Hu - Author 2 contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 3 - Qiaofeng Wu - Author 3 checked the manuscript.