Effectiveness and safety of Liuhe Pill for treating gout: A protocol for a systematic review and meta-analysis

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Review question / Objective: P: Patients with gout; I: Treat with Liuhe Pill; C: Treat without Liuhe Pill; O: duration of pain and the proportion of subjects achieving the target serum urate level at month 6; S: RCTs.

Condition being studied: Liuhe Pill is used to treat gout in China. But at present, there is no systematic evaluation report on its therapeutic effectiveness and safety. This protocol aims to reveal the efficacy and safety of Liuhe Pill for treating gout.

Information sources: We will search the Web of Knowledge, EMBASE WANFANG DATA, CNKI, PubMed, ClinicalTrials.gov and Cochrane Library from inception to October 31, 2021 to retrieve relevant studies. We will also search citations of relevant primary and review. Authors of abstract in the meeting will be further searched in PubMed for potential full articles. To minimize the risk of publication bias, we will conduct a comprehensive search that included strategies to find published and unpublished studies.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 March 2021 and was last updated on 07 March 2021 (registration number INPLASY202130019).

INTRODUCTION

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METHODS

Participant or population: The inclusion criteria for the study will include: (1) studies with adult patients who has a diagnosis of gout; (2) conference abstracts were only included when they provided adequate relevant information for assessment; (3) the patients with gout were divided into two groups (treated with Liuhe Pill or without Liuhe Pill); Exclusion criteria will include: age <18 years old, and patients with incomplete data.

Intervention: Treat with Liuhe Pill.

Comparator: Treated without Liuhe Pill.

Study designs to be included: RCTs.

Eligibility criteria: The inclusion criteria for the study will include: (1) studies with adult patients who has a diagnosis of gout; (2) conference abstracts were only included when they provided adequate relevant information for assessment; (3) the patients with gout were divided into two groups (treated with Liuhe Pill or without Liuhe Pill); Exclusion criteria will include: age <18 years old, and patients with incomplete data.

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Main outcome(s): Duration of pain and the proportion of subjects achieving the target serum urate level at month 6.

Quality assessment / Risk of bias analysis: Risk of bias assessment will be carried out according to the Newcastle-Ottawa Scale (NOS) to rate the internal validity of the individual studies, and funnel plots will be constructed to assess the risk of publication bias.

Strategy of data synthesis: All pairwise meta-analytic calculations will be performed with Review Manager software (RevMan) version 5.3 (Cochrane Collaboration). Heterogeneity will be examined by computing the Q statistic and I² statistic, and presence of reporting bias by visual inspection of funnel plots. Statistical significance was considered when the P value <0.05.

Subgroup analysis: Patients with gout treated with Liuhe Pill and patients with gout treated without Liuhe Pill.

Sensitivity analysis: All pairwise meta-analytic calculations will be performed with Review Manager software (RevMan) version 5.3 (Cochrane Collaboration). Heterogeneity will be examined by computing the Q statistic and I² statistic, and presence of reporting bias by visual inspection of funnel plots. Statistical significance was considered when the P value <0.05.

Country(ies) involved: China.

Keywords: Gout; Liuhe Pill; Traditional Chinese medicine; prognosis.

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