INPLASY PROTOCOL

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Conflicts of interest:
None declared.

The effectiveness and safety of Wu tou decoction on rheumatoid arthritis: A protocol for systematic review and/or meta-analysis

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Review question / Objective: **The purpose of systematic review and meta-analysis is to verify the clinical effectiveness and safety of Wu tou decoction as a treatment on rheumatoid arthritis.**
Condition being studied: **Several studies reported that Wu tou decoction can decrease the levels of interlukin-1β, tumor necrosis factor-α, and prostaglandin E2. Wu tou decoction has been known to have anti-inflammatory effect by decreasing the percentage of CD4+ cells in the inflammatory arthritis rat model.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 February 2022 and was last updated on 23 February 2022 (registration number INPLASY202220099).

INTRODUCTION

Review question / Objective: **The purpose of systematic review and meta-analysis is to verify the clinical effectiveness and safety of Wu tou decoction as a treatment on rheumatoid arthritis.**

Rationale: **Wu tou decoction has been known to be useful to rheumatoid arthritis with anti-inflammatory action, however there has been no systematic review (SR) about it.**

Condition being studied: **Several studies reported that Wu tou decoction can decrease the levels of interlukin-1β, tumor necrosis factor-α, and prostaglandin E2. Wu tou decoction has been known to have anti-inflammatory effect by decreasing the**

percentage of CD4+ cells in the inflammatory arthritis rat model.

METHODS

Search strategy: We will search randomized controlled trials about the Wu tou decoction for rheumatoid arthritis through multiple electronic databases, manual search, and contact to author.

Participant or population: Patients who is diagnosed as rheumatoid arthritis.

Intervention: Wu tou decoction

Comparator: Other conservative treatments for rheumatoid arthritis, including placebos, medications, and physiotherapy. The use of concomitant combination therapy with Wu tou decoction should be coincide with the experimental group and the control group.

Study designs to be included: A randomized controlled trial (RCT) examining the effects of Wu tou decoction on rheumatoid arthritis will be included with a control group that includes other classical therapies.

Eligibility criteria: We will only include randominzed controlled trials (RCTs). Non-RCTs and uncontrolled clinical trials are excluded. There are no restrictions on language or neither publications

Information sources: Searches will be performed on the following databases from the initiation to June 2022 : MEDLINE, Cochrane Library, China National Knowledge Infrastructure (CNKI), CiNii, J-STAGE, KoreaMed, Korean Medical Database, Korean Studies Information Service System (KISS), National Digital Science Library (NDSL), Korea Institute of Science and Technology Information (KISTI), and Oriental Medicine Advanced Searching Integrated System (OASIS). There are no restrictions on language and the searches will be based on the language provided by each database.

Main outcome(s): Disease activity score including effective rate, swollen joint count, tender joint count, morning stiffness.

Additional outcome(s): Blood test about RA including ESR, CRP, RF, and adverse events.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess the risk of bias using the "Risk of Bias" tool from the Cochrane Collaboration. This consists seven areas: sequence generation, assignment concealment, blinding participants and investigators, blinding outcome raters, incomplete outcome data, selective outcome reporting, and other biases. The risk of bias for each domain is assessed as "low risk", "high risk", or "ambiguous risk".

Strategy of data synthesis: Review Manager (REVMAN) software for Windows will be use to perform a meta-analysis and to calculate the RR or SMD (Version 5.3; Copenhagen; The Nordic Cochrane Center, The Cochrane Collaboration, 2014). Calculate pooled estimates of effect sizes using either a random effects model or a fixed effects model with 95% CI.

Subgroup analysis: Potentially if the data are suitable.

Sensitivity analysis: We will perform a sensitivity analysis to test the robustness of study finding.

Country(ies) involved: Republic of Korea.

Keywords: rheumatoid arthritis, Wu tou decoction, systematic review, meta-analysis.

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