INPLASY PROTOCOL

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Conflicts of interest:
None declared.

The effectiveness and safety of Duantengyimu-tang for rheumatoid arthritis: A protocol for systematic review and meta-analysis

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Review question / Objective: **Regardless of pharmacological effects of Duantengyimu-tang (DTYMT)'s component, there is also concern about the safety. Therefore, this systematic review (SR) will focus on the effectiveness and safety of DTYMT on rheumatoid arthritis (RA).**
Information sources: **MEDLINE, Cochrane Library, China National Knowledge Infrastructure, CiNii, J-STAGE, KoreaMed, Korean Medical Database, Korean Studies Information Service System, National Digital Science Library, Korea Institute of Science and Technology Information, and Oriental Medicine Advanced Searching Integrated System.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 April 2023 and was last updated on 27 April 2023 (registration number INPLASY202340100).

INTRODUCTION

Review question / Objective: **Regardless of pharmacological effects of Duantengyimu-tang (DTYMT)'s component, there is also concern about the safety. Therefore, this systematic review (SR) will focus on the effectiveness and safety of DTYMT on rheumatoid arthritis (RA).**

Rationale: **As the treatment type by taking medication, several decoctions have been reported its effectiveness and safety, and recent study introduced DTYMT.**

Condition being studied: **DTYMT is consisted of three main components (Phlomis umbrosa, Leonurine herba, and Tripterygium hypoglaucum Hutch), and several experimental studies have reported**

these herbs' pharmacological effects related to arthritis, suggesting that it may be effective in treating RA. However, there are also questions about the safety of DTYMT, especially Tripterygium hypoglaucum Hutch, because it's toxicity has been frequently mentioned.

METHODS

Search strategy: We will use the electronic databases mainly. The researchers will search for the study from the initiation to August 2023 and use search terms for RA (e.g., rheumatoid arthritis, rheumatoid) and DTYMT (Duantengyimu-tang, Duantengyimu-decoction).

Participant or population: RA patients.

Intervention: Duantengyimu-tang (DTYMT).

Comparator: conservative treatments for RA including medication, injection, and physiotherapy.

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

Eligibility criteria: This SR will include only RCTs that have investigated the effects of DTYMT on RA and compared conservative treatments.

Information sources: MEDLINE, Cochrane Library, China National Knowledge Infrastructure, CiNii, J-STAGE, KoreaMed, Korean Medical Database, Korean Studies Information Service System, National Digital Science Library, Korea Institute of Science and Technology Information, and Oriental Medicine Advanced Searching Integrated System.

Main outcome(s): Disease activity scores including effective rate, tender joint, swollen joint, and morning stiffness will be the main (primary) outcomes.

Additional outcome(s): Blood test used in RA diagnosis (erythrocyte sedimentation rate, C-reactive protein, rheumatoid factors) and adverse events will be secondary outcomes.

Quality assessment / Risk of bias analysis: The reviewer will independently evaluate the risk of bias using Cochrane Collaboration "Risk of bias". These are seven domains (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 will be assessed as "low risk", "high risk", or "unclear risk".

Strategy of data synthesis: This SR will use Review Manager software (version 5.3; Copenhagen; The Nordic Cochrane Center, The Cochrane Collaboration, 2014) for meta-analysis. Use the change from baseline to completion of the intervention and calculate the mean difference and 95% confidence interval in the same outcome measurement, and the standardized mean difference and 95% confidence interval in different outcome measurements.

Subgroup analysis: If 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: Duantengyimu-tang, rheumatoid arthritis, systematic review, meta-analysis.

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