

INPLASY PROTOCOL

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None declared.

The effectiveness and safety of Duhuo Jisheng decoction combined with the medication on rheumatoid arthritis: A study protocol for systematic review and meta-analysis

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Review question / Objective: We are going to investigate the effectiveness and safety of Duhuo Jisheng decoction (DHJSD) with medication for Rheumatoid arthritis (RA).

Condition being studied: A randomized controlled trial (RCT) showed that DHJSD significantly relieved the clinical symptoms of RA, CRP, ESR, and RF comparing to the control group.

Information sources: 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) will be used to search for related studies published from initial time of each database to June 2022, There is no language restriction and the search will be performed according to the language provided by each database.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 February 2022 and was last updated on 24 February 2022 (registration number INPLASY202220105).

INTRODUCTION

Review question / Objective: We are going to investigate the effectiveness and safety of Duhuo Jisheng decoction (DHJSD) with medication for Rheumatoid arthritis (RA).

Rationale: The representative treatment for RA is medication including DMARDs and

NSAIDs. However, these medications have limitations and other complementary and alternative medicines are gaining interest. Although several studies reported the effectiveness of DHJSD on RA, systematic review on effectiveness and safety of DHJSD with medication was not yet provided.

Condition being studied: A randomized controlled trial (RCT) showed that DHJSD significantly relieved the clinical symptoms of RA, CRP, ESR, and RF comparing to the control group.

METHODS

Search strategy: We will search related RCT through multiple electronic databases, manual search, and contact to author.

Participant or population: Patients diagnosed as RA.

Intervention: Duhuo Jisheng decoction with conventional medication for RA.

Comparator: Patients can undergo any type of conventional medication monotherapy including DMARDs and NSAIDs.

Study designs to be included: RCTs that compared the effects of DHJSD with medication on RA with control group containing conventional medication treatments will be included.

Eligibility criteria: We will only include RCTs. Non-RCTs and uncontrolled clinical trials (eg, case studies) will be excluded. There will be no limitation according to language or publication.

Information sources: 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) will be used to search for related studies published from initial time of each database to June 2022, There is no language restriction and the search will be performed according to 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, and RF, and adverse events.

Quality assessment / Risk of bias analysis: Risk of bias will be assessed by two reviewers independently using the Chochrane "risk of bias" tool. The tool is composed of seven domains: sequence generation, allocation concealment, blinding of participants and investigators, blinding of outcome assessors, incomplete outcome data, selective outcome reporting, and other biases. The risk of bias will be rated as "low risk," "high risk," or "unclear risk" for each domain.

Strategy of data synthesis: We will use the Review Manager (REVMAN) software for Windows to perform a meta-analysis and combine the changes from baseline to completion of the intervention in the included studies. The mean difference (same outcome measure) or standardized mean difference (different outcome measures) and 95% confidence intervals (CIs) will be calculated to estimate the effect with a random-effects or a fixed-effect model.

Subgroup analysis: Potentially if data suitable based on the main intervention in control group.

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

Country(ies) involved: Republic of Korea.

Keywords: rheumatoid arthritis, Duhuo Jisheng decoction, medication, systematic review, meta-analysis.

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