

INPLASY PROTOCOL

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The authors declare no conflicts of interest.

A comparative study of the efficacy of Chinese herbal medicine Duhuo Jisheng decoction combined with DMARDs versus isolated DMARDs for Rheumatoid arthritis: Protocol for systematic review and meta-analysis

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Review question / Objective: The aim of this review is to evaluate the effectiveness of Duhuo Jisheng decoction combined with Disease-modifying anti-rheumatic drugs compared with isolated Disease-modifying anti-rheumatic drugs for Rheumatoid arthritis.

Condition being studied: Rheumatoid arthritis (RA) is a chronic autoimmune system disease that mainly affects joints throughout the body, causing joint pain, deformity, and even disability. While bringing great pain to the patients, it also increases the social burden. In terms of treatment, Disease-modifying anti-rheumatic drugs (DMARDs) can improve the condition, chronic course and prognosis of patients with RA due to their anti-inflammatory and immunomodulatory or immunosuppressive effects. Therefore, they are preferentially recommended for use and have achieved good clinical effects. However, the therapeutic effect of a single anti-rheumatic drug is sometimes not ideal. Combining other western drugs may aggravate side effects or increase the incidence of adverse reactions.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 October 2020 and was last updated on 23 October 2020 (registration number INPLASY2020100089).

INTRODUCTION

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METHODS

Search strategy: CNKI, Wanfang, VIP, CBM, PubMed, Embase and Cochrane Library databases were searched for this study. Take the subject terms combined with free words to search, take PubMed as an example: terms consist of disease (Arthritis, Rheumatoid OR Rheumatoid Arthritis) and intervention (Duhuo Jisheng decoction OR Duhuo Jisheng Tang) and Comparison (Antirheumatic Agents OR DMARDs OR Methotrexate OR Sulfasalazine OR Leflunomide OR Iguratimod) and research types (randomized controlled trial OR controlled clinical trial OR random trials).

Participant or population: Patients were diagnosed with rheumatoid arthritis and the study belongs to randomized controlled trial. Clinical results included clinical effectiveness, Rheumatoid factor (RF), Erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), symptom evaluation (including morning stiffness, pain and joint swelling), and adverse effects. Experimental group must cover Duhuo Jisheng decoction combined with Disease-modifying anti-rheumatic drugs (DMARDs) and control group must cover Disease-modifying anti-rheumatic

drugs (DMARDs). Otherwise, studies will be excluded if they cannot meet the inclusion criteria.

Intervention: Intervention of the experimental group must cover Duhuo Jisheng decoction combined with Disease-modifying anti-rheumatic drugs (DMARDs). There are no restrictions on the way of dosage and treatment period.

Comparator: The control group must cover Disease-modifying anti-rheumatic drugs (DMARDs).

Study designs to be included: Only randomized controlled trials will be included in this study.

Eligibility criteria: Randomized clinical trials will be included irrespective of blinding, publication status or language.

Information sources: We will search articles in seven electronic database including: CNKI, Wanfang, VIP, CBM, PubMed, Embase and Cochrane Library databases. All the publications, with no time restrictions, will be searched without any restriction of countries or article type. Reference list of all selected articles will independently screened to identify additional studies left out in the initial sea.

Main outcome(s): The primary outcome is symptom evaluation (including the number of swelling joints affected by RA; the number of painful joints affected by RA; the duration of morning stiffness).

Additional outcome(s): The secondary outcome are clinical effectiveness, Rheumatoid factor (RF), Erythrocyte sedimentation rate (ESR), C-reactive protein (CRP) and adverse effects.

Data management: (1) NoteExpress and Excel software will be used to extract data, and the content will be stored in electronic chart. (2) Different researchers will separately screen the titles and abstracts of records acquired potential eligibility which comes from the electronic

databases. Full texts screening and data extraction will be conducted afterwards independently. Any disagreement will be resolved by discussion until consensus is reached or by consulting a third author. In this step, we will use NoteExpress. (3) The following data will be extracted: author, year of publication, country, interventions of experimental groups and control groups, time point, outcome measures, age of patients, total number of people included in the study, patients' basic information, etc. Different researchers will separately extract data. Any disagreement regarding data extraction will be resolved by discussion until consensus is reached or by consulting a third author. In this step, we will use Excel.

Quality assessment / Risk of bias analysis:

Two reviewers will independently assess the quality of the selected studies according to the Cochrane Collaboration's tool for randomized controlled trials. Items will be evaluated in three categories: Low risk of bias, unclear bias and high risk of bias. The following characteristics will be evaluated: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), incomplete outcome data (attrition bias), selective reporting (reporting bias) and other biases. Results from these questions will be graphed and assessed using Review Manager 5.4. The results will be presented in the form of a graph, and will be independently evaluated by two researchers. If there are differences of opinion, they will be discussed with the third researcher.

Strategy of data synthesis: Statistical analysis will be conducted using RevMan 5.4 software. For continuous data, will be used mean difference (MD) as the effect indicator with 95% confidence interval, and dichotomous data will be calculated as risk ratio (RR) or odds ratio (OR) as the effect index with 95% confidence interval. If the studies with no statistical homogeneity, the fixed-effect model can be used for analysis; if the studies with significant statistical

heterogeneity, random effects model analysis will be used.

Subgroup analysis: We will consider subgroups analysis the course of disease, and the intervention time.

Sensitivity analysis: Through sensitivity analysis assess the source of heterogeneity, by excluding low-quality studies, or by excluding one of the included studies in turn, if there is no significant change in the heterogeneity, the results are robust, otherwise, the excluded study is heterogeneous originate.

Language: No restriction on language.

Country(ies) involved: China.

Keywords: systematic review; protocol; Duhuo Jisheng decoction; Disease-modifying anti-rheumatic drugs; Rheumatoid arthritis; randomized controlled trial.

Dissemination plans: We plan to publish a systematic review based on this protocol.

Contributions of each author:

Author 1 - Xing Zhou - Drafted and improved the manuscript.

Author 2 - Kemeng Xiang - Revise this protocol; search strategy; analysis of results.

Author 3 - Minyuan Lu - data collection.