INPLASY PROTOCOL

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Efficacy and Safety of Modified Duhuo Jisheng Decoction in the Treatment of Lumbar Disc Herniation: A Systematic Review and Meta-Analysis

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Review question / Objective: **The purpose of our meta-analysis is to evaluate the efficacy and safety of modified DHJSD in the treatment of LDH.**
Condition being studied: **Lumbar disc herniation (LDH) is based on the degenerative changes of the intervertebral disc. Many drugs are used to treat and prevent LDH, including Western medicine and Chinese medicine. Duhuo Jisheng Decoction (DHJSD) is one of the more classic Chinese medicine prescriptions. The purpose of our meta-analysis is to evaluate the efficacy and safety of modified DHJSD in the treatment of LDH.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 June 2020 and was last updated on 14 June 2020 (registration number INPLASY202060053).

INTRODUCTION

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METHODS

Participant or population: **Patients with LDH who received modified DHJSD and Western medicine, respectively.**

Intervention: This meta-analysis compares the effects of modified DHJSD and different western medicines on LDH.

Comparator: Different western medicines, including diclofenac sodium enteric-coated tablets, ibuprofen, iclofenac sodium sustained release capsule, and indomethacin.

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

Eligibility criteria: All trials included in our study meet the following criteria: (1) All patients included in these RCTs were diagnosed with LDH based on symptoms, signs, and imaging features; (2) All included studies were original RCTs; (3) In all included studies, the experimental group received modified DHJSD, while the control group received Western medicine; (4) Studies published in Chinese or English; (5) The full text of the included literature can be obtained, and the measurement data of total effective rate, cure rate, and visual analogue scale (VAS) scores can be extracted.

Information sources: We searched for the following terms "Duhuo Jisheng Decoction or DHJSD", "lumbar disc herniation", "herniated disc or disk", and "disc or disk, herniated" with the Boolean operators "AND or OR" by using Medical Subject Headings (MeSH) terms and corresponding keywords. The corresponding Chinese translation of the search strategy will be used for the Chinese database search. Then, two researchers independently screened the above-retrieved literature by reading the titles and abstracts. Finally, the selected literature should be further filtered by reading the full text. After the discussion, all disagreeable literature was resolved.

Main outcome(s): Total effective rate and cure rate are the primary outcome measurements. VAS scores are the secondary outcome measurements.

Quality assessment / Risk of bias analysis: Two researchers independently conducted a quality assessment of each included RCT according to the Cochrane Handbook for Systematic Reviews.

Strategy of data synthesis: The continuous data was analyzed by using weighted mean difference (WMD) and 95% confidence interval (CI). The dichotomous data was analyzed by using risk ratio (RR) and their 95% CI, such as blood transfusion rate. The heterogeneity of the included studies was evaluated using the $\chi 2$ test and I2 test. When the value of I2 is 25%, 50% and 75%, it is regarded as low, medium and high heterogeneity. When I2> 50%, P<0.1, we performed a random-effect model; otherwise, a fixed-effect model was performed.

Subgroup analysis: We conducted a subgroup analysis of the total effective rate and cure rate based on the use of Western medicine.

Sensibility analysis: Sensitivity analysis was conducted to assess the stability of the pooled result. We use Stata software for sensitivity analysis. We found that when excluding any study, the results did not find significant changes, thus confirming the robustness and reliability of the results of this meta-analysis.

Country(ies) involved: China.

Keywords: Duhuo Jisheng Decoction; Western medicine; Lumbar disc herniation; Pain management.

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