

INPLASY PROTOCOL

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Corresponding author:
Zenan Wu

a3265640@126.com

Author Affiliation:
Jiangxi University of
Traditional Chinese Medicine

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5141900101

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The authors declare no conflicts of interest.

The effectiveness of moxibustion for treating of Lumbar Disc Herniation(LDH): a protocol for systematic review and meta-analysis

Wu, ZN¹; Xiong, J²; Xie, QS³; Yang, Y⁴.

Review question / Objective: To compare the effectiveness of moxibustion therapie including heat-sensitive moxibustion, direct moxibustion, indirect moxibustion, and conventional drug therapy for lumbar disc herniation(LDH).

Condition being studied: Lumbar disc herniation (LDH) refers to lumbar disc degeneration or external pressure, resulting in annulus fibrosus rupture, nucleus pulposus protrusion or bulging, compression of nerve roots, cauda equina nerve, and then some clinical symptoms of a clinical syndrome, clinical symptoms are often manifested as unilateral or bilateral lumbar pain, leg numbness. L3/L4,L4/L5, and L5/S1 intervertebral disc herniations are common in the lesion sites of lumbar disc herniations, and the incidence rate is as high as 90%. Typical manifestations are tenderness at the corresponding surface of the body. This disease is a common and frequently-occurring disease in the department of rehabilitation and acupuncture of the hospital, and is a common cause of lumbago and leg pain. At present, the common external treatment for LDH includes many methods, mostly acupuncture and moxibustion.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 July 2020 and was last updated on 10 July 2020 (registration number INPLASY202070034).

INTRODUCTION

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METHODS

Participant or population: Patients with lumbar disc disease will be included, and we will screen them for gender, age, race, region, etc.

Intervention: Moxibustion include direct moxibustion, indirect moxibustion and other types of moxibustion.

Comparator: Control group: including, medication, placebo or other treatment.

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

Eligibility criteria: Only randomized controlled trials will be included in this study.

Information sources: We're going to use systematic electronic search, including PubMed,MEDLINE, Cochrane library, SinoMed, China National Knowledge Infrastructure (CNKI), WangFang Database(WF), and Chinese Scientific Journal Database (VIP).

Main outcome(s): The severity of the pain and the relief of symptoms. Measures of

effect. Visual analog scale (VAS) and Follow-up records during the trial.

Additional outcome(s): 1.Function or disability (e.g. Japanese Orthopaedic Association Scores, Oswestry Disability Index). 2.Quality of life(QoL); 3.Adverse events. Measures of effect. From baseline to the last available follow-up.

Data management: According to the inclusion and exclusion criteria, two researchers screened literatures and extracted literature information, including the following aspects: 1) study characteristics: author, year, study design, sample size, and follow-up time; 2) patient characteristics: age, pain level, and accompanying symptoms; 3) intervention: intervention measures, moxibustion and treatment methods, acupuncture point selection, moxibustion quantity and moxibustion time in the experimental group; intervention measures in the control group: acupuncture method, acupuncture point name, treatment retention time, treatment type, treatment frequency, treatment frequency and duration; 4) study outcome: visual analogue scale (VAS), functional or disability, adverse events, therapeutic effect, side effects were assessed for pain severity. The results of the two researchers were cross-referenced to the included literature. In case of disagreement, a third party should be consulted for resolution.

Quality assessment / Risk of bias analysis: Two of our researchers will use the bias risk tool provided by the Cochrane Collaboration to evaluate the quality of the literature using RevMan 5.3 software. This recommended tool includes 7 important items: sequence generation, allocation concealment, blinding of participants and personnel, blinding of results evaluation, incomplete result data, selective result reporting, and other biases. Make "Low risk," "High risk," and "unclear risk" judgments for each research literature. Finally, a "risk of deviation" summary and a chart are generated to show the results. As with the previous process, it will be independently assessed by 2 researchers.

If there is disagreement, it will be discussed with the 3rd researcher.

Strategy of data synthesis: The RevMan 5.3.3 software was used for Meta analysis of the research objects. The relative risk (RR) and 95%CI were used for the counting data, and the mean difference (MD) and 95%CI were used for the measurement data. The heterogeneity among the included results was tested by 2 test. If the results of each study showed statistical homogeneity ($P > 0.1$, $I^2 < 50\%$), the fixed effect model was used for meta-analysis of the results. If there is statistical heterogeneity in the results of each study ($P < 0.1$, $I^2 > 50\%$), the source of the heterogeneity should be analyzed; if there is statistical heterogeneity in the results of two studies and the difference in the results is not statistically significant, the random effect model should be used for meta-analysis. When there is too much heterogeneity among the results, statistical methods such as subgroup analysis, sensitivity analysis and descriptive analysis can be used to deal with it.

Subgroup analysis: We will conduct a subgroup analysis based on the integrity of the evidence collected, and try to trace the source of heterogeneity based on the age of participants, stage of onset, differences in intervention measures, controls and outcome measures.

Sensibility analysis: To assess the influence of each individual study, leave-one-out sensitivity analysis was performed iteratively by removing one study at a time to confirm that the findings were not influenced by any single study.

Language: English.

Country(ies) involved: China.

Keywords: moxibustion; Lumbar Disc Herniation; systematic review; meta-analysis.

Contributions of each author:

Author 1 - Zenan Wu - conceive and design this protocol.

Author 2 - Jun Xiong - Revise this protocol; search strategy.

Author 3 - Qionshan Xie - Data collection; analysis of results.

Author 4 - Yi Yang - Analysis of results.