INPLASY PROTOCOL

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Corresponding author:
Jingyu Wang

724813694@qq.com

Author Affiliation:
Shandong University of Chinese MedicineThe Second Affiliated Hospital of Shandong University of Chinese Medicine.

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Conflicts of interest:
None declared.

Acupuncture for the treatment of degenerative lumbar spinal stenosis A protocol for systematic review and meta analysis

Wang, JY[1]; Liu, ZL[2]; Guan, H[3]; Zhang, YC[4]; Jia, HL[5].

Review question / Objective: **This meta-analysis aims to assess the effectiveness of acupuncture in treating DLSS, which could allow to provide a basis for clinical decision-making.**
Condition being studied: **Degenerative lumbar spinal stenosis (DLSS) is a common condition secondary to degenerative changes. Its clinical manifestations include intermittent claudication and back, gluteal and lower extremity pain and fatigue. Acupuncture has been gradually accepted around the world for its safe and green characteristics. At present, there has been no systematic evaluation on acupuncture treatment of DLSS. Therefore, this study aims to evaluate the efficacy and safety of acupuncture in the treatment of DLSS to provide evidence for clinical decision making.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 August 2022 and was last updated on 23 August 2022 (registration number INPLASY202280093).

INTRODUCTION

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changes. Its clinical manifestations include intermittent claudication and back, gluteal and lower extremity pain and fatigue. Acupuncture has been gradually accepted around the world for its safe and green characteristics. At present, there has been no systematic evaluation on acupuncture treatment of DLSS. Therefore, this study aims to evaluate the efficacy and safety of acupuncture in the treatment of DLSS to provide evidence for clinical decision making.

METHODS

Search strategy: The following electronic databases will be searched from their initiation to August 2022: Embase, PubMed, Medline, Cochrane Library, Web of Science, China National Knowledge Infrastructure (CNKI), VIP, WanFang, China Biology Medicine Database (CBM). The search strategy used Medical Subject Heading terms and free words and then used Boolean logic operators to connect each search item.The retrieval strategy of PubMed has been detailed in Table 1, which was adapted for use in other databases.

Participant or population: We will consider patients with a clinical diagnosis of DLSS irrespective of their age, gender, race, country, severity, and disease duration. Both the patient and the family informed the study and signed a consent form.

Intervention: The experimental group is defined as acupuncture treatment,such as manual acupuncture, electric acupuncture, fire acupuncture, warm acupuncture, scalp acupuncture, ear acupuncture, skin acupuncture,uricular acupuncture,or moxibustion.

Comparator: The control group that will include non-acupuncture techniques, such as conventional symptomatic treatment, drug treatment, sham acupuncture, placebo acupuncture, or no treatment. The acupoint numbers, frequency, and retaining time will not be restricted in this protocol.

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

Eligibility criteria: This review will include randomized controlled trials (RCTs) on acupuncture for DLSS published in Chinese and English. Review studies, expert clinical experience, non-RCTs, animal experiments, and case reports.

Information sources: The following electronic databases will be searched from their initiation to August 2022: Embase, PubMed, Medline, Cochrane Library, Web of Science, China National Knowledge Infrastructure (CNKI), VIP, WanFang, China Biology Medicine Database (CBM).

Main outcome(s): Pain intensity, disability and functional status will be evaluated as the primary outcome. Pain intensity is measured by a visual analog scale or other pain scale, such as visual analog scale (VAS), numerical rating scale (NRS), McGill pain scale . Disability and functional status are measured by a back pain-specific scale, such as Oswestry Disability Index (ODI), Roland Morris Disability Questionnaire (RMDQ).

Additional outcome(s): Hospital Anxiety and Depression Scale (HADS) and adverse reactions will be evaluated as the secondary outcomes.

Data management: The data will be independently extracted by 2 researchers (JYW and ZLL) using a uniform data form. The following information will be extracted according to the CONSORT statement format: the journal title, first author, year of publication, study design, patient characteristics, control intervention, experimental intervention, outcomes, duration of intervention, etc. If there is any disagreement, it will be resolved through discussion between two reviewers. If it can't be agreed, a third-party reviewer will decide.

Quality assessment / Risk of bias analysis: Two researchers (JYW and ZLL) will access the risk of bias employing the Cochrane Deviation Risk Collaborative Tool for

Systematic Reviews of Interventions, which comprises 7 items: sequence generation, allocation hiding, blindness, incomplete data evaluation, selective results reporting, and other sources of bias. The assessment of risks of bias will be classified into three levels: low risk of bias, high risk of bias and unclear risk of bias.

Strategy of data synthesis: If studies are adequately homogeneous in design and comparison, we will conduct data synthesis using RevMan 5.4 software. The fixed-effects or random-effects model will be chosen depending on the I2 value. A 95% confidence interval will be the effective size for data synthesis. We will perform qualitative analysis if the data is not fit for quantitative analysis.

Subgroup analysis: We will conduct subgroup analysis according to the following groups to explore the causes of heterogeneity. 1. Types of acupuncture. 2. Length of treatment, and duration, frequency.

Sensitivity analysis: If the result shows high heterogeneity (the I2 test is>75%), we will perform sensitivity analysis to examine the robustness and reliability of merged outcome results with the exclusion of small and low-quality studies. Then we will acquire a stable result of our study.

Language restriction: The language of the publication is limited.

Country(ies) involved: China.

Keywords: Degenerative lumbar spinal stenosis, acupuncture, meta-analysis, protocol.

Contributions of each author:

Author 1 - Jingyu Wang.
Email: 724813694@qq.com
Author 2 - Ziliang Liu.
Author 3 - Hong Guan.
Author 4 - Yongchen Zhang.
Author 5 - Hongling Jia.