

INPLASY PROTOCOL

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Effectiveness and safety of warm needle acupuncture for sciatica: A protocol for systematic review and meta-analysis

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Review question / Objective: To evaluate the effectiveness and safety of warm needle acupuncture for sciatica.

Condition being studied: Sciatica is a syndrome characterized by sciatic nerve path and distribution area pain. Its typical symptoms include radiation pain in one or both lower limbs, sometimes accompanied by numbness, which can be manifested as pain in the waist, buttock, back of thigh, posterolateral leg and lateral dorsum of foot. The disease is prone to recurrent attacks, greatly reducing the patient's work efficiency and quality of life. In recent years, many literatures reported the definite effect of warm needle acupuncture (WNA) on sciatica. This study will provide an assessment of the current state of WNA for the sciatica, aiming to show the effectiveness and safety of WNA treatment.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 November 2020 and was last updated on 18 November 2020 (registration number INPLASY2020110074).

INTRODUCTION

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by numbness, which can be manifested as pain in the waist, buttock, back of thigh, posterolateral leg and lateral dorsum of foot. The disease is prone to recurrent attacks, greatly reducing the patient's work efficiency and quality of life. In recent years, many literatures reported the definite effect of warm needle acupuncture (WNA) on sciatica. This study will provide an assessment of the current state of WNA for the sciatica, aiming to show the effectiveness and safety of WNA treatment.

METHODS

Search strategy: The electronic databases, including PubMed, Cochrane Library, EMBASE, the China National Knowledge Infrastructure (CNKI), China Biology Medicine disc (CBM), VIP database and Wanfang database, were thoroughly retrieved from inception to December 1st, 2021, without language restrictions.

Participant or population: Patients with sciatica include those diagnosed with sciatica, such as radiculopathy, nerve root injury, nerve root compression, nerve root pain, and pain knee radiation to the lower part, which are not limited by sex, age, nationality and race.

Intervention: WNA, or WNA combine with other conventional treatments.

Comparator: The control group was given western medicine, placebo, conventional acupuncture, sham acupuncture, no treatment and other conventional treatment.

Study designs to be included: All randomized controlled trials (RCTs) that evaluated the efficacy and safety of WNA in the treatment of sciatica will be included.

Eligibility criteria: Subjects: patients with sciatica, sex, age, nationality and race were not restricted. Intervention measures: warm needle acupuncture, or warm needle acupuncture with other routine treatments were used as the intervention measures in the treatment group, while conventional acupuncture or other therapy was used as

the intervention measures in the control group. Outcome measures: the visual analogue scale (VAS), Short-Form McGill Pain Questionnaire (SF-MPQ), and Oswestry Disability Index (ODI).

Information sources: We will use computers to retrieve all RCTs of WNA on PubMed, Cochrane Library, EMBASE, CNKI, Wanfang, CBM and VIP databases. At the same time, we will supplement it by searching relevant literature manually.

Main outcome(s): The visual analogue scale (VAS), Short-Form McGill Pain Questionnaire (SF-MPQ), and Oswestry Disability Index (ODI).

Quality assessment / Risk of bias analysis: To assess the risk of bias for all included studies, Cochrane Collaboration's bias risk tool will be used by two independent review authors to assess the following areas: random sequence generation, allocation concealment, blindness to participants, people, and results, incomplete outcome data, optional reporting, and other biases. Any discrepancies in the deviation risk assessment will be resolved through discussion. Ultimately, the quality of the studies will be divided into three levels: low risk of bias, high risk of bias, and unclear risk of bias.

Strategy of data synthesis: All analyses will be conducted by using RevMan software (V5.4). We will select fixed effects model or random effects model to merge the outcome indicators in accordance with the results of heterogeneity test. The fixed effects model will be applied for data synthesis of low heterogeneity ($I^2 < 50\%$) while the random effects model will be conducted if the heterogeneity is significant ($I^2 \geq 50\%$). It is considered that differences are statistically significant if the results of Z test show that P value is less than 0.05, and the 95% CI does not contain 0 (for continuous variables) or the 95% CI does not contain 1 (for dichotomous variables).

Subgroup analysis: We will perform the following subgroup analyses if included data are highly heterogeneous: by age, sex, sample size, acupoints, highly heterogeneous.

Sensitivity analysis: If the heterogeneity of the included literature is significant, in order to ensure the credibility of the research results, we will conduct sensitivity analysis by excluding each included study separately, so as to improve the research quality.

Language: Chinese and English.

Country(ies) involved: China.

Keywords: Warm needle acupuncture, sciatica, meta analysis, systematic review, protocol.

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