INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Efficacy of Electroacupuncture in Painful Diabetic Peripheral Neuropathy: A protocol of systematic review and meta-analysis

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Review question / Objective: **The aim of this study is to perform a meta-analysis to evaluate the effectiveness of electroacupuncture in the treatment of painful diabetic peripheral neuropathy (PDNP).And to provide data support for electroacupuncture as an effective means to treat pain of nervous system diseases.**
Condition being studied: **Diabetes mellitus (DM) affects more than six hundred million population worldwide till 2045. The most common form is chronic, distal, and symmetric sensorimotor polyneuropathy, while other uncommon forms include asymmetric or focal neuropathy, such as diabetic muscle atrophy, trunk radiculopathy, and compression palsy. About 11.4% and 40.5% of patients have severe and moderate pain respectively. Currently, symptomatic treatment of PDPN is based on the application of medications that target the symptoms of PDPN. However, the clinical efficacy of PDPN patients varies greatly from individual to individual.Traditional Chinese medicine electroacupuncture have shown its unique advantages in the treatment of PDPN. Although its mechanism is complex and unclear, it can still be used in the clinical treatment of PDPN for a long time. We therefore present a systematic review of the benefits of electroacupuncture in improving PDPN by including the as many as possible randomized controlled trials.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 November 2022 and was last updated on 09 November 2022 (registration number INPLASY2022110040).

INTRODUCTION

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METHODS

Search strategy: Electronic searches - We will search articles in electronic databases including PubMed, Embase, the Web of Science, Cochrane Library, China National Knowledge Infrastructure, WanFang database, China Science Technology Journal Database (VIP) and the China Doctor/Master Dissertations Full-text Database. All the publications to 30 October 2022 will be searched. Also, by searching the WHO International Clinical Trials Registry Platform, Chinese Clinical Trial Registry and ClinicalTrials. gov, we will retrieve unpublished protocols and overview findings. Our approach uses a combination of subject and free words and will be decided after several pre-searches. At the same time, the original literature of all the study references will be searched to supplement and obtain relevant literature and ensure a high recovery rate. An example of the search strategy for the Medical Search Headings that will be used is presented in table 1. For Chinese databases, Chinese translations of these search terms will be used. This approach will adapt and incorporate similar search techniques for other electronic databases. Other search methods Specific conference papers will be manually retrieved and the experts in the field will contact the corresponding authors to obtain valuable information that cannot be accessed by the above data retrieval process.

Participant or population: This analysis will include studies on adult patients 18 years of age or older who have been diagnosed with PDPN according to the diagnostic criteria from the WHO, the American Diabetes Association and the diagnostic criteria for DPN from the International Association for Pain Research. No constraints will be placed on regional data, educational background, race and gender.

Intervention: Patients in the treatment group will be given electroacupuncture without restrictions on the needle content, choice of treatment point, mode of procedure, the retention time of the needle and course of treatment. Interventions without stimulating acupoints combined with two or more therapies or with potential safety problems will be excluded. Studies regarding electroacupuncture as adjunctive treatment compared with other treatments will also be included.

Comparator: Primary controls included: sham acupuncture, positive drugs, and rehabilitation therapy.

Study designs to be included: We will include all randomized controlled trials (RCTs) regarding electroacupuncture in treating PDPN. Nonrandomized clinical studies, cluster randomized trials, and quasi-randomized trials will be excluded. The language is limited to English and Chinese.

Eligibility criteria: Types of studies. We will include all randomized controlled trials (RCTs) regarding electroacupuncture in treating PDPN. Nonrandomized clinical

studies, cluster randomized trials, and quasi-randomized trials will be excluded. The language is limited to English and Chinese. Type of participants This analysis will include studies on adult patients 18 years of age or older who have been diagnosed with PDPN according to the diagnostic criteria from the WHO, the American Diabetes Association and the diagnostic criteria for DPN from the International Association for Pain Research. No constraints will be placed on regional data, educational background, race and gender. Type of interventions. Patients in the treatment group will be given electroacupuncture without restrictions on the needle content, choice of treatment point, mode of procedure, the retention time of the needle and course of treatment. Interventions without stimulating acupoints combined with two or more therapies or with potential safety problems will be excluded. Studies regarding electroacupuncture as adjunctive treatment compared with other treatments will also be included. Types of outcome measures. The main outcomes will include superficial peroneal nerve sensory nerve conduction velocity (SCV), bilateral dorsal current perception threshold (CPT) values of the first toe, the Michigan Diabetic Peripheral Neuropathy Screening Inventory (MNSI), the Neuropathic Pain Symptom Inventory (NPSI), the Leeds Neuropathic Signs and Symptoms Score (LANSS), the Brief Pain Inventory (BPI) and the McGill Pain Questionnaire. Secondary outcomes The secondary outcomes for the study will be fasting glucose, serum C-peptide, blood lipids, glycated serum protein and the depression and anxiety status of the patients withPDPN.

Information sources: Electronic searches - We will search articles in electronic databases including PubMed, Embase, the Web of Science, Cochrane Library, China National Knowledge Infrastructure, WanFang database, China Science Technology Journal Database (VIP) and the China Doctor/Master Dissertations Full-text Database. All the publications to 30 October 2022 will be searched. Also, by searching the WHO International Clinical Trials Registry Platform, Chinese Clinical Trial Registry and ClinicalTrials. gov, we will retrieve unpublished protocols and overview findings. Our approach uses a combination of subject and free words and will be decided after several pre-searches. At the same time, the original literature of all the study references will be searched to supplement and obtain relevant literature and ensure a high recovery rate. An example of the search strategy for the Medical Search Headings that will be used is presented in table 1. For Chinese databases, Chinese translations of these search terms will be used. This approach will adapt and incorporate similar search techniques for other electronic databases. Other search methods Specific conference papers will be manually retrieved and the experts in the field will contact the corresponding authors to obtain valuable information that cannot be accessed by the above data retrieval process. In the case of studies where data are missing, the researcher will attempt to obtain information by contacting the corresponding author of the study. We will build our research on the available data if communication is unsuccessful.

Main outcome(s): The main outcomes will include superficial peroneal nerve sensory nerve conduction velocity (SCV), bilateral dorsal current perception threshold (CPT) values of the first toe, the Michigan Diabetic Peripheral Neuropathy Screening Inventory (MNSI), the Neuropathic Pain Symptom Inventory (NPSI), the Leeds Neuropathic Signs and Symptoms Score (LANSS), the Brief Pain Inventory (BPI) and the McGill Pain Questionnaire.

Additional outcome(s): Secondary outcomes The secondary outcomes for the study will be fasting glucose, serum C-peptide, blood lipids, glycated serum protein and the depression and anxiety status of the patients with PDPN.

Quality assessment / Risk of bias analysis: The risk of bias will be assessed using the Cochrane Risk of Bias Assessment Method, 30 which focuses on selection (including random sequence generation

and allocation concealment), implementation (including blinding of researchers and subjects), evaluation (blinded study outcomes assessment), follow-up (competence of outcome data), reporting (selective study outcomes reporting) and other sources of bias. For a total of seven entries in six fields, the probability of bias will be assessed (other sources of bias). Based on the risk of bias evaluation criteria, 'low risk of bias', 'high risk of bias' and 'unclear' will be calculated for each entry. Review Manager statistical software (RevMan) V.5.4 will produce a graphical presentation of the risk evaluation of bias.

Strategy of data synthesis: We will use Review Manager Software(RevMan)V.5.3 for data synthesis, meta-analysis. Mean difference or standardized mean differenceand 95% confidence intervals (CIs) will be used to calculate quantitative data, and dichotomous data will be exerted as risk ratio and 95% CIs. Statistical heterogeneity across studies will be done with I^2 statistic.$I^2 \leq 50$ indicates homogeneity among studies, and a fixed-effects model will be employed for pooled analysis.$I^2 > 50\%$ suggests obvious heterogeneity, and a random-effects model will be employed for synthesized analysis. When there is the homogeneity of the merged outcome results across sufficient studies, meta-analysis will be conducted.

Subgroup analysis: If necessary, the data will be analysed in groups according to different factors such as differences in the acupuncture method, frequency of treatment and the follow-up time.

Sensitivity analysis: Sensitivity analysis will be used to assess the stability of the meta-analysis results based on the following criteria: study quality, sample size, missing data, quality of heterogeneity, and statistical model.

Language restriction: The language is limited to English and Chinese.

Country(ies) involved: China.

Keywords: electroacupuncture;painful diabetic peripheral neuropathy;meta-analysis, systematic review.

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