INPLASY PROTOCOL

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None declared.

The Efficacy and Safety of Chinese Herbal Medicine in The Treatment of Diabetic Painful Neuropathy：A Systematic Review and Meta-Analysis

Song, M[1]; Shi, ZP[2]; Liu, ZG[3]; Li, R[4]; Liu, ZG[5].

Review question / Objective: **This study aims to evaluate the efficacy and safety of Chinese herbal medicine in the treatment of diabetic painful neuropathy.**
Condition being studied: **Diabetic painful neuropathy is one of the common complications of diabetic peripheral neuropathy. The incidence of the disease ranges from 13% to 24%. It is clinically characterized by spontaneous pain, induced pain, hyperalgesia, hyperalgesia and so on, which seriously affects the quality of life of patients. At present, anticonvulsant drugs and opioids are often used to relieve the pain. Although these drugs can relieve the symptoms of patients, long-term use exerts serious side effects and patients' compliance is not strong. Chinese herbal medicine has a long history of understanding and treatment of the disease and clinical studies have shown that Chinese herbal medicine is effective in relieving pain symptoms and improving the pathological progress of neuropathy.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 April 2022 and was last updated on 24 April 2022 (registration number INPLASY202240144).

INTRODUCTION

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drugs can relieve the symptoms of patients, long-term use exerts serious side effects and patients' compliance is not strong. Chinese herbal medicine has a long history of understanding and treatment of the disease and clinical studies have shown that Chinese herbal medicine is effective in relieving pain symptoms and improving the pathological progress of neuropathy.

METHODS

Search strategy: The following online databases will be comprehensively searched including: The Cochrane Library, PubMed, EMBASE, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure Database (CNKI), Chinese Science and Technique Journals Database (VIP), and the Wanfang Database. All the literature retrieved is from the inception of the database to 21 April 2022. There are no language restrictions or regional restrictions. Missing literature information will be supplemented by contacting the original author.

Participant or population: Participants who were definitely diagnosed with diabetic painful neuropathy would be included, and there will be no limitation on sex, ages, and other factors.

Intervention: The experimental group was treated with Chinese herbal medicine or conventional treatment combined with Chinese herbal medicine.

Comparator: The control group adopted placebo, painkillers, or no treatment.

Study designs to be included: All randomized controlled trials (RCTs) about Chinese herbal medicine for diabetic painful neuropathy will be included regardless of language.

Eligibility criteria: Inclusion criteria: (1) Included were randomized controlled trials in any language. (2) Patients were enrolled with clear criteria for disease diagnosis, regardless of race, sex and age. (3) Patients in the experimental group received TCM treatment for more than 4 weeks. Exclusion criteria: (1) Non-rct studies, animal studies, and reviews. (2) Acupuncture, massage and other non-Traditional Chinese medicine treatment. (3) Intermittent treatment or treatment of less than 4 weeks. (4) No clear diagnostic criteria or concomitant diseases.(5) Duplicate publications or literatures with incomplete basic information.

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Main outcome(s): Clinical efficacy, visual analogue scale (VAS) and improvement of nerve conduction velocity were the main results.

Additional outcome(s): Secondary outcomes included fasting blood glucose, 2-hour postprandial blood glucose, quality of life score, depressive status score, and adverse events.

Data management: Two researchers independently screened literatures, extracted data and cross-checked them. Disputes, if any, shall be resolved through discussion or consultation with a third party. In literature screening, the title should be read first, and the abstract and full text should be further read to determine whether to include or not after the exclusion of obviously irrelevant literature. If necessary, contact the original author by email or telephone to obtain information that is not identified but is important to this

study. Data extraction includes: (1) Basic information of included studies: research title, first author, published journal, etc.; (2) Baseline characteristics and interventions of subjects; (3) Key elements of bias risk assessment; (4) Outcome indicators and outcome measurement data concerned.

Quality assessment / Risk of bias analysis: wo researchers independently evaluated the risk of bias in the included studies and cross-checked the results. The RCT bias risk assessment tool recommended by Cochrane Journal 5.1.0 was used to assess the risk of bias.

Strategy of data synthesis: The Review Manager 5.3 software was used to analyze the data. Relative risk (RR) and standardized mean difference (SMD) were used as effect sizes for counting data and measurement data respectively. 95% confidence intervals (CI) were used for calculation of both effect sizes. The chi-square text was used to analyze the heterogeneity of the research, if the heterogeneity is tiny ($P \geq 0.1$, $I2 \leq 50\%$) ,then choose the fixed effects model, otherwise ($P < 0.1$, $I2 > 50\%$), further analysis of sources of heterogeneity is necessary. After ruling out the influence of the clinical heterogeneity, random effects model for Meta analysis can be used.

Subgroup analysis: If there is significant heterogeneity between studies, subgroup analysis will be performed on patients of different ages and genders.

Sensitivity analysis: Furthermore, if necessary, a sensitivity analysis will be performed.

Language: We will not limit language being imposed on the search.

Country(ies) involved: China.

Keywords: Chinese herbal medicine; diabetic painful neuropathy; efficacy and safety ; Systematic review; Meta-analysis.

Contributions of each author:
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Author 3 - Zhenguo Liu.
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