INPLASY PROTOCOL

To cite: Zhang et al. Danggui Sini Decoction for treating diabetic peripheral neuropathy: a protocol of systematic review and meta-analysis of randomized controlled trials. Inplasy protocol 202040157. doi: 10.37766/inplasy2020.4.0157

Received: 23 April 2020

Published: 23 April 2020

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Support: **None.**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest: **None known.**

Danggui Sini Decoction for treating diabetic peripheral neuropathy: a protocol of systematic review and meta-analysis of randomized controlled trials

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Review question / Objective: **Is Danggui Sini Decoction (DSD) beneficial for diabetic peripheral neuropathy (DPN)?**
Condition being studied: **Diabetic peripheral neuropathy (DPN) is a common chronic complication of diabetes. It is hidden and has a significant impact on the quality of life of patients. Early identification and treatment of DPN is of great significance for patients' prognosis.**
Information sources: **PubMed, Web of Science, Embase, the Cochrane Library, the Chinese National Knowledge Infrastructure Database (CNKI), Wangfang and the VIP database.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 April 2020 and was last updated on 23 April 2020 (registration number INPLASY202040157).

INTRODUCTION

Review question / Objective: **Is Danggui Sini Decoction (DSD) beneficial for diabetic peripheral neuropathy (DPN)?**

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METHODS

Search strategy: **Relevant literature was retrieved using multiple online databases**

including PubMed, Web of Science, Embase, the Cochrane Library, the Chinese National Knowledge Infrastructure Database (CNKI), Wangfang and the VIP database. No limits were imposed on study dates or publication language, type, and status. The key terms used in these searches were: "diabetic peripheral neuropathy", "Danggui Sini Decoction", "Danggui Sini Tang", "Danggui Sini". Different search strategies were used for the Chinese and foreign language databases. In addition, the reference lists of previously published systematic reviews on the subject of DSD for the treatment of DPN were manually examined for pertinent studies.

Participant or population: Adults with clinically diagnosed diabetic peripheral neuropathy.

Intervention: Danggui Sini Decoction (DSD) is a classical prescription described in Shanghan Zabing Lun, written by Zhang Zhongjing during the Han dynasty. Studies that used any type of DSD or a modified DSD are included, as are studies comparing the effects of DSD alone or combined with conventional medication (NSAID or OCP) to the effects of conventional medicine alone. A modified DSD is defined by practitioners as a DSD with no more than one of the original herbs, but which had the same action as the original DSD formula. We include all forms of this medication, such as extracts, tablets, capsules, pills, powders, and injections. Studies examining DSD combined with other herbal decoctions or with other types of therapy are excluded. Trials in which the DSD is used as an adjunct to conventional treatment, usual care, or standard care are included if the control group received the same concomitant treatment as the DSD group.

Comparator: No current/recent DSD use.

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

Eligibility criteria: Participants: The patients of DPN must meet the diagnostic criteria established by the 2016 Chinese Medical Association Diabetes Branch, regardless of race, sex, and age. Neuropathy caused by other causes and patients with severe heart disease, liver and kidney dysfunction, mental illness, or a relevant drug allergic history will be not included. Interventions: Both groups were cured with conventional diabetes treatments recommended by the ADA guidelines, including diet, exercise, and hypoglycemic, and lipid-lowering therapies. The experiment group used DSD or modified DSD, while the control group applied for placebo, nutritional neurological drugs, or no treatment. In addition, the 2 groups did not take any drugs that interfered with the outcome indicators. The follow-up time was ≥4 weeks.

Information sources: PubMed, Web of Science, Embase, the Cochrane Library, the Chinese National Knowledge Infrastructure Database (CNKI), Wangfang and the VIP database.
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Main outcome(s): Clinical efficacy.

Additional outcome(s): Clinical total efficiency.

Data management: Results of searches will be stored in EndNote and reviewed in Covidence. Titles and abstracts will be screened by one reviewer with 10% checked by a second reviewer. The full text will be retrieved for all records identified as potentially eligible. Full texts will be reviewed for eligibility by two reviewers in duplicate, with a third author consulted to resolve any discrepancies. Data will be extracted and entered into a pre-defined and piloted Microsoft Excel Database. Data will be extracted by one reviewer and independently checked by a second reviewer. Discrepancies will be identified and resolved through discussion (with a third author where necessary). Data items to be extracted will include study design; number of participants in each group; Control group intervention; nerve conduction velocity; blood glucose; blood viscosity; duration of follow-up; unadjusted and adjusted effect estimates with

confidence intervals; information required for risk of bias assessments.

Quality assessment / Risk of bias analysis: The Cochrane risk of bias tool will be used to assess the risk of bias in Randomised Controlled Trials (https://methods.cochrane.org/bias/resources/rob-2-revised-cochrane-risk-bias-tool-randomized-trials), and the ROBINS-I tool (Risk Of Bias In Non-randomized Studies - of Interventions: http://www.riskofbias.info/welcome/home) for non-randomised studies. Assessments will be carried out by two reviewers independently, with discrepancies discussed with a third reviewer to reach a consensus. Sensitivity analyses will be conducted to assess how excluding studies at high risk of bias influences the findings.

Strategy of data synthesis: For each study effect estimates and 95% confidence intervals will be calculated using intention-to-treat principles. Statistical heterogeneity will be assessed using the Cochran ?² test (Q?test), with the I² statistic used to assess the percentage of variability between studies that is due to heterogeneity rather than to sampling error. Meta-analysis will be used to pool the effect estimates, using fixed-effect or random-effects methods (depending on heterogeneity). Meta-regression will be used to assess the study-level factors contributing to heterogeneity across studies.

Subgroup analysis: If the necessary data are available, subgroup analyses will be conducted for with different comparators separately.

Sensibility analysis: Sensitivity analysis is mainly used to evaluate the robustness of the primary outcome measures. The method is that removing the low-level quality study one by one and then merge the data to assess the impact of sample size, study quality, statistical method, and missing data on results of meta analysis.

Language: English.

Country(ies) involved: China.

Keywords: Diabetic peripheral neuropathy, Danggui Sini Decoction, Protocol, Systematic review.

Contributions of each author:
Author 1 - Conceptualization, Resources, Software.
Author 2 - Data curation, Project administration, Supervision.
Author 3 - Data curation, Formal analysis, Supervision.
Author 4 - Formal analysis, Resources, Software, Supervision.
Author 5 - Methodology.
Author 6 - Methodology.
Author 7 - Conceptualization, Funding acquisition, Project administration.