INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Acupuncture for diabetic foot: A protocol for a systematic review and meta-analysis

Gong, YB[1]; Yang, YS[2]; Wang, SY[3]; Li, XF[4]; Pan, T[5]; Chen, CH[6]; Chen, XH[7].

Review question / Objective: **The purpose of this protocol was to explore the effect of acupuncture on patients with DF and to provide more options for clinicians and patients to treat DF.**
Condition being studied: **Diabetic foot(DF) is one of the most common complications in diabetic patients, accounting for 60%–80% of diabetic patients, and has been widely applied in the treatment of diabetic foot. However, its efficacy has not yet been evaluated scientifically or systematically. Therefore, we provide a protocol for systematic evaluation to assess the effectiveness and safety of acupuncture treatment in patients with diabetic foot disease.**
Information sources: **Electronic data sources Six electronic databases from inception to July 2022 will be searched: PubMed, Embase, Cochrane Library, Chinese databases Sino-Med, Chinese National Knowledge Infrastructure (CNKI), and Wanfang databases.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 September 2022 and was last updated on 03 September 2022 (registration number INPLASY202290009).

INTRODUCTION

Review question / Objective: **The purpose of this protocol was to explore the effect of acupuncture on patients with DF and to provide more options for clinicians and patients to treat DF.**

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METHODS

Search strategy: Electronic data sources Six electronic databases from inception to July 2022 will be searched: PubMed, Embase, Cochrane Library, Chinese databases Sino-Med, Chinese National Knowledge Infrastructure (CNKI), and Wanfang databases.

Participant or population: The Patients aged 18 years or older suffering from DF will be included in this review, regardless of gender, race, or occupation.

Intervention: We will include studies in which intervention groups applied acupuncture alone or in combination with other forms of treatment, such as Chinese herbal medicine and Western medicine.

Comparator: The control group underwent drug treatment and did not undergo any acupuncture intervention (electro-acupuncture, warm acupuncture, auricular acupuncture, scalp acupuncture, dry needling, acupoint injection, press needle, acupressure, acupoint catgut embedding, etc.).

Study designs to be included: Only RCTs were included in the present review, including traditional acupuncture, warm-needle techniques, and electroa-cupuncture. No publication date or language restrictions were imposed during the initial search. RCTs

Eligibility criteria: Participants who were pregnant, breastfeeding, menstruating, or suffering from other serious illnesses were excluded. Wagner grade evaluation levels of 0 to 4 were included.

Information sources: Electronic data sources Six electronic databases from inception to July 2022 will be searched: PubMed, Embase, Cochrane Library, Chinese databases Sino-Med, Chinese National Knowledge Infrastructure (CNKI), and Wanfang databases.

Main outcome(s): The primary outcome is the total curative effective rate. Secondary outcomes include the hemodynamic parameter and side effects caused by acupuncture.

Quality assessment / Risk of bias analysis: The two reviewers will independently use the bias tool of the Cochrane Handbook for Systematic Reviews of Interventions[12] to evaluate the risk of bias of the final included studies. The evaluated items included random sequence generation, allocation concealment, blinding of participants, personnel and outcomes, incomplete outcome data, selective reporting, and other biases. 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: Heterogeneity was assessed using the Cochran Q statistic and quantified using the I2 statistic. If I2 was >50%, the studies were considered heterogeneous, and a random-effects model was used. A fixed-effects model was implemented if the I2 was < 50%. I2 (25–50%) indicated moderate heterogeneity.

Subgroup analysis: Subgroup analysis will be implemented according to administration type and outcome measures when there is substantial heterogeneity.

Sensitivity analysis: If necessary, we will carry out a sensitivity analysis to assess the quality and robustness when significant statistical heterogeneity arises according to sample size and insufficient data.

Country(ies) involved: Changchun University of ChineseMedicine, Changchun, China.

Keywords: acupuncture, diabetic foot, protocol, systematic review, meta-analysis

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