INPLASY PROTOCOL

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The authors have no conflict of interest to disclose.

The Safety and Efficacy of Astragalus for treating diabetic foot ulcers. A protocol for systematic review and meta-analysis

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Review question / Objective: **The aim of this meta-analysis of randomized controlled trials is to evaluate the efficacy and safety of effectiveness and safety of Astragalus for treating diabetic foot ulcers during the past 10 years.**
Condition being studied: **Diabetic foot ulcers are the most common complication in diabetic patients. The annual incidence of foot ulceration among people with diabetes is about 9.26 million. About 80% of nontraumatic lower-extremity amputations are presented with foot ulceration, which provides a portal for infection. Furthermore, diabetic patients who suffer from foot ulcers encounter financial burden on health five times higher than those without foot ulcers. Astragalus as a Chinese herbal medicine has been reported in many publications that it can treat diabetic foot ulcers by increasing the number of body fibroblasts, promote cell proliferation, reducing the activity of galactosidase in ulcers, improving cell aging and delaying cell aging. However, there is currently no systematic review of the safety and effectiveness of Astragalus in the treatment of diabetic foot ulcer. Therefore, we propose a protocol for a systematic review to evaluate the effectiveness and safety of in the treatment of diabetic foot ulcers.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 November 2020 and was last updated on 15 November 2020 (registration number INPLASY2020110059).

INTRODUCTION

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METHODS

Participant or population: The studies will involve adult participants who meet the diagnostic criteria for diabetic foot ulcer. All eligible study participants will be included in this review, regardless of gender, race or occupation. Study participants who are pregnant, breastfeeding, menstruating or suffering from other serious illnesses will be excluded.

Intervention: We will include all randomized controlled trials which uses Astragalus alone(e.g. oral administration, topical use) or in combination with other medical interventions.

Comparator: The control group was treated with commonly used western medicine (such as Buflomedil, Urokinase, Ozagrel, Recombinant Human Growth Hormone,DL-Thioctic acid etc.), placebo or no intervention measures.

Study designs to be included: Only randomized controlled trials (RCTs) can be included. Observation studies, animal experiment, case report, review, and meta-analysis are excluded.

Eligibility criteria: Participants/population The studies will involve adult participants who meet the diagnostic criteria for diabetic foot ulcer. All eligible study participants will be included in this review, regardless of gender, race or occupation. Study participants who are pregnant, breastfeeding, menstruating or suffering from other serious illnesses will be excluded. Interventions /exposure we will include all randomized controlled trials which uses Astragalus alone(e.g. oral administration, topical use) or in combination with other medical interventions. Comparators/Control: The control group was treated with commonly used western medicine (such as Buflomedil, Urokinase, Ozagrel, Recombinant Human Growth Hormone, DL-Thioctic acid etc.), placebo or no intervention measures. Types of study to be included Only randomized controlled trials (RCTs) can be included. Observation studies, animal experiment, case report, review, and meta-analysis are excluded.

Information sources: The following databases will be searched from 1st January 2010 to September 2020: The Cochrane Library, Pubmed, EMBASE, Web of Science, China National Knowledge Infrastructure and Wanfang Data. All the English and Chinese publications be searched without any restriction of countries.

Main outcome(s): The rate of healing based on the Wagner classification.

Quality assessment / Risk of bias analysis: The methodological quality of RCTs will be assessed by Cochrane risk of bias. It includes generation of the allocation sequence; concealment of the allocation sequence; blinding; attrition and exclusions; other generic sources of bias; biases specific to the trial design (such as crossover or cluster randomized trials); and biases that might be specific to a clinical specialty. Any disagreement will be addressed by discussion among authors.

Strategy of data synthesis: The analysis and synthesis of data will be conducted by RevMan 5.4.1. The random-effects model and the fixed-effects model will be applied, when I2 is more than50% and I2 is less than 50% respectively. Risk ratio with 95% confidence interval (CI). will be used to determine dichotomous data and weighted mean differences (with 95% CI) or standardized mean differences (95%) CI will be used to analyze the continuous data.

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

Sensibility analysis: If necessary, a sensitivity analysis will be performed.

Country(ies) involved: China.

Keywords: diabetic foot ulcer, Astragalus, meta-analysis.

Contributions of each author:

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