INPLASY PROTOCOL

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Conflicts of interest:
The authors have no conflicts of interest to disclose.

The safety and efficacy of Sclerosing Foam on treating Venous leg ulcers: protocol for systematic review and meta analysis

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Review question / Objective: **Whether Sclerosing Foam can be safe and efficient on treating Venous leg ulcers.**
Condition being studied: **Venous leg ulcers (VLUs) are common throughout the world, which seriously affects the patient's work and life. Relevant researches suggested that sclerosing foam (SF) has potential benefits for VLUs. However, there is no consistent conclusion.**
Information sources: **Eight databases will be searched from inception to May 2020: PubMed, the Cochrane Library, EMBASE, Web of Science, China National Knowledge Infrastructure Database (CNKI), Wanfang Database, China Science and Technology Journal Database, and Chinese Biological Medicine. There are no article language restrictions.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 July 2020 and was last updated on 02 July 2020 (registration number INPLASY202070003).

INTRODUCTION

Review question / Objective: **whether Sclerosing Foam can be safe and efficient on treating Venous leg ulcers.**

Condition being studied: **Venous leg ulcers (VLUs) are common throughout the world, which seriously affects the patient's work and life. Relevant researches suggested that sclerosing foam (SF) has potential benefits for VLUs. However, there is no consistent conclusion.**

METHODS

Search strategy: **Relevant clinical randomized controlled trials (RCTs) will be obtained from a search of eight databases (with no language restrictions) from their inception to May 2020: PubMed, the Cochrane Library, EMBASE, Web of Science, China National Knowledge**

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Infrastructure Database (CNKI), Wanfang Database, China Science and Technology Journal Database, and Chinese Biological Medicine.

Participant or population: The adult patients (aged 18 years or older) who have been confirmedly diagnosed with VLUs.

Intervention: We will include studies that use any type of SF intervention, alone or as an adjunct to standard medical care for VLUs (liquid sclerotherapy will be excluded).

Comparator: We will compare this to a control group that receives standard medical care alone (without SF), or a control intervention other than SF.

Study designs to be included: Only RCTs about Sclerosing Foam on treating Venous leg ulcers will be included, non-randomised trials and observational studies will be excluded.

Eligibility criteria: The Diagnostic Criteria for VLUs: Refer to the Evidence-based (S3) guidelines for diagnostics and treatment of venous leg ulcers.

Information sources: Eight databases will be searched from inception to May 2020: PubMed, the Cochrane Library, EMBASE, Web of Science, China National Knowledge Infrastructure Database (CNKI), Wanfang Database, China Science and Technology Journal Database, and Chinese Biological Medicine. There are no article language restrictions.

Main outcome(s): Closure of venous leg ulcers Ulcer healing rate (UHR) Adverse events related to SF (such as phlebitis, deep vein thrombosis).

Additional outcome(s): Ulcer healing time (UHT) Ulcer recurrence rate (URR) Pain related to VLUs (measured using any validated scales, such as verbal rating scale (VRS), or Visual Analogue Scale (VAS).

Quality assessment / Risk of bias analysis: According to the Cochrane Handbook standards[22], the evaluation will include the following seven aspects: random sequence generation (selection bias); distribution data hiding (selection bias); blinding (implementation bias) of researchers and implementers; results of the blind evaluation (measurement bias); completeness of outcome data (follow-up bias); results of selective reporting (reporting bias); and other sources of bias. Each item will be divided into three risk levels (low risk, unclear risk, high risk). Two researchers will independently evaluate the included literature and any disagreement will be resolved by consultation with a third party.

Strategy of data synthesis: Risk ratio (RR) will be used for categorical data; mean differences (MD) will be used for measurement data, and 95% confidence intervals (CI) will be used.

Subgroup analysis: We plan to carry out the following subgroup analyses if there are adequate studies: Dose of SF (diFerent drug concentrations and frequencies) Period of follow up Geographical area We will use the formal test for subgroup interactions in Review Manager.

Sensibility analysis: We will use sensitivity analysis to determine whether our results are robust. We will exclude the studies with high risk for bias from the summary analysis and analyze them again to assess the impact of these studies on the results.

Language: No.

Country(ies) involved: China.

Keywords: Sclerosing Foam, Venous leg ulcers, effect, safety.

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