INPLASY PROTOCOL

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Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest: **None.**

Efficacy of prostaglandina E1 for the treatment of patients with thrombo-occlusive vasculitis: a protocol of systematic review and meta-analysis

Sun, Y[1]; Wang, HR[2]; Feng, XH[3]; Wang, KF[4].

Review question / Objective: **Is prostaglandina E1 (PE1) effective for the treatment of patients with thrombo-occlusive vasculitis (TOV)?**
Condition being studied: **Thrombo-occlusive vasculitis, and prostaglandina E1.**
Information sources: **The following electronic databases (Cochrane Library, PubMed, EMBASE, Web of Science, Scopus, the Allied and Complementary Medicine Database, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure) will be sought from commencement to the March 1, 2020 with no limitations to language and publication status. All potential RCTs that investigated the efficacy of PE1 for the treatment of patients with TOV will be included. Search strategy sample for Cochrane Library will be presented. We will adapt equivalent search strategies for other electronic databases. We will seek secondary literature sources to avoid missing potential studies, such as Google Scholar, conference abstracts, and reference lists of relevant reviews.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 April 2020 and was last updated on 14 April 2020 (registration number INPLASY202040081.

INTRODUCTION

Review question / Objective: **Is prostaglandina E1 (PE1) effective for the treatment of patients with thrombo-occlusive vasculitis (TOV)?**

Condition being studied: **Thrombo-occlusive vasculitis, and prostaglandina E1.**

METHODS

Participant or population: **We will include patients who were diagnosed as TOV, in spite of their race, age, gender, and severity of TOV.**

Intervention: **In the experimental group, all patients received PE1 for their solely treatment will be included.**

Comparator: **In the control group, there are no limitations to any comparators, such as herbal medicine. However, we will exclude**

studies which involved PE1 as their controls.

Study designs to be included: This study will include randomized controlled trials (RCTs) of PE1 for the treatment of patients with TOV.

Eligibility criteria: This study will include RCTs of PE1 comparing with other managements for the treatment of patients with TOV.

Information sources: The following electronic databases (Cochrane Library, PubMed, EMBASE, Web of Science, Scopus, the Allied and Complementary Medicine Database, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure) will be sought from commencement to the March 1, 2020 with no limitations to language and publication status. All potential RCTs that investigated the efficacy of PE1 for the treatment of patients with TOV will be included. Search strategy sample for Cochrane Library will be presented. We will adapt equivalent search strategies for other electronic databases. We will seek secondary literature sources to avoid missing potential studies, such as Google Scholar, conference abstracts, and reference lists of relevant reviews.

Main outcome(s): Primary outcomes include hemorheological indicators (such as blood fluidity, viscosity, deformability and coagulation of high-cut blood viscosity, low-cut blood viscosity, plasma specific viscosity, and red cell aggregation index).

Additional outcome(s): Secondary outcomes consist of skin temperature of the affected limb, ankle brachial index, painless walking distance, maximum walking distance, ulcer area of the affected limb, serological indicators, recurrence rate, incidence of complications (such as infection, coagulopathy, secondary thrombosis) and amputation rate.

Data management: Two reviewers will separately perform data extraction using pre-constructed data extraction sheet. Different opinions will be solved by discussion with the help of a third reviewer. The extracted information consists of general trial information (e.g. first author, year of publication), patient baseline characteristics (e.g. gender, age, disease severity and duration), trial methods (e.g. randomization, blind), details of intervention and controls, outcomes, adverse events, and other related information.

Quality assessment / Risk of bias analysis: Two reviewers will independently evaluate the risk of bias of all eligible RCTs using Cochrane risk of bias tool. It comprises of 7 domains and each item is graded as high, unclear, or low risk of bias. Any differences will be solved by discussion with the help of a third reviewer.

Strategy of data synthesis: This study will use RevMan 5.3 software for statistical analysis. To summarize the effects of PE1 treatment for each trial, weighted mean difference or standardized mean difference and 95% confidence intervals (CIs) will be utilized when the result is continuous data. In case of dichotomous data, risk ratio and 95% CIs will be exerted. I^2 test is utilized to check statistical heterogeneity. A fixed-effects model will be employed if there is homogeneity across the data ($I^2 \leq 50\%$), and a random-effects model will be applied if obvious heterogeneity is present ($I^2 > 50\%$). If necessary, we will carry out a meta-analysis. Otherwise, we will perform a subgroup analysis if considerable heterogeneity is found.

Subgroup analysis: Subgroup analysis will be utilized to investigate the sources of heterogeneity based on the different treatments, controls, and outcomes.

Sensibility analysis: Sensitivity analysis will be required to test the robustness of conclusions by removing low quality studies.

Country(ies) involved: China.

Keywords: Thrombo-occlusive vasculitis; prostaglandina E1; efficacy.