INPLASY PROTOCOL

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Conflicts of interest: None declared.

INTRODUCTION

Review question / Objective: Plaque psoriasis (PSO) is a common chronic inflammatory skin disease that presents a series of characteristics such as stubbornness, difficulty in curing, and ease of recurrence. The vicious cycle of itching, scratching, and aggravation of lesions seriously affect patients' quality of life and physical and mental health, and its incidence is increasing. Prickingbloodletting cupping therapy (PBCT) is a traditional Chinese medicinal, external treatment method, that has been widely used in clinical practice and has a good curative effect. With inadequate clinical

Pricking-bloodletting cupping therapy for plaque psoriasis: A protocol for systematic review and meta-analysis

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INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 September 2022 and was last updated on 30 September 2022 (registration number INPLASY202290126). systematic reviews and evidence-based medical evidence, this systematic evaluation protocol aims to describe a meta-analysis to assess the effectiveness and safety of PBCT in the treatment of patients with PSO.

Condition being studied: Plague psoriasis (PSO) is an abnormal skin disease with abnormal immune mechanisms due to polygenic genetic regulation, which is associated with multifactorial stimuli such as infections, vascular, psychoneurological, and environmental drugs. The pathogenesis of psoriasis is complex and unclear, therefore its treatment has been a hot and difficult point in dermatology. About 1-3% of the world's population suffers from this disease, and the incidence of psoriasis in China is approximately 0.47%, with an increasing trend in recent years. PSO presents as a well-defined dark red plaque covered with thick layers of silvery-white scales with a flushed infiltrated base, which makes patients often feel intense pruritus. The patient may have a sense of stigma, anxiety, depression, and other psychological states, and can even develop suicidal tendencies in that the disease can appear in any part of the body and has the characteristics of persistence, recurrence, and persistence. Pruritus is an obvious symptom in patients with PSO which can interfere with their daily life and rest because there is a vicious cycle of itching-scratching-aggravation of lesions. Despite the fact that prickingbloodletting cupping therapy (PBCT) for PSO is widely used in clinical practice and has good efficacy, there has been no metaanalysis of the efficacy of PBCT for PSO. Therefore, we conduct this study to objectively evaluate the efficacy and safety of PBCT in the treatment of PSO and to seek a more objective evidence-based basis for clinical practice.

METHODS

Search strategy: From the establishment date to September 2022, databases including PubMed, MEDLINE, EMBASE, Cochrane Library, China Knowledge Base Database (CNKI), Wan Fang Database, China Scientific Journal Database (VIP), and China Biomedical Database (CBM) will be searched, and randomized controlled trials (RCTs) related to prickingbloodletting cupping therapy (PBCT) for plaque psoriasis-related randomized controlled trials (RCTs) will be extracted. In addition, other eligible documents such as references, and conference papers will be manually retrieved.

Participant or population: All participants included in this study must meet the diagnostic criteria for PSO, regardless of the patient's sex, age, race, severity, duration of treatment, or medical unit.

Intervention: The treatment group will include studies on PBCT, combination drugs, and other combination therapies. There will be no restrictions on the PBCT material or frequency of treatment.

Comparator: The control group will include untreated or with one or more interventions (pharmacotherapy, placebo, UV irradiation therapy, physical exercise, and so on).

Study designs to be included: This systematic evaluation will include all RCTs of PBCT for PSO.

Eligibility criteria: (1) Types of studies: This systematic evaluation will include all RCTs of PBCT for PSO. (2) Types of participants: All participants included in this study must meet the diagnostic criteria for PSO, regardless of the patient's sex, age, race, severity, duration of treatment, or medical unit. (3) Type of interventions: The treatment group will include studies on PBCT, combination drugs, and other combination therapies. There will be no restrictions on the PBCT material or frequency of treatment. (4) Type of comparator: The control group will include untreated or with one or more interventions (pharmacotherapy, placebo, UV irradiation therapy, physical exercise, and so on).

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Main outcome(s): Main outcomes include treatment effectiveness and Psoriasis Area and Severity Index (PASI).

Additional outcome(s): The Dermatology Life Quality Index (DLQI), relapse rate, and adverse events will be accepted as additional outcomes.

Data management: Two researchers will independently extract data from the selected articles. Disagreements will be resolved by referring to the original article and discussing it with a third investigator. The extracted data will include the following information: first author, year of publication, sample size, study methods, interventions, participant characteristics, outcomes, and adverse events. Data will be stored in Microsoft Excel.

Quality assessment / Risk of bias analysis:

Two researchers will use the Cochrane Risk of Bias tool to assess the methodological quality of RCTs. The following seven aspects are included: random sequence generation, allocation concealment, the blindness of participants and caregivers, the blindness of outcome evaluators, incomplete outcome data, selective outcome reports, and other biases. The assessment results of each project will be classified as high-risk, lowrisk, or unclear risk. The divergences will be submitted to a third investigator for a final decision.

Strategy of data synthesis: The extracted data will be synthesized and subjected to a meta-analysis using RevMan V.5.4. We will

use a fixed-effects or random-effects model based on the results of the heterogeneity test. If the data are not suitable for quantitative analysis, we will provide a descriptive analysis to address this issue.

Subgroup analysis: If there is significant heterogeneity among all study outcomes, we will perform subgroup analyses according to the study type, intervention method, treatment frequency, and different PSO evidence types.

Sensitivity analysis: If significant heterogeneity exists, we will perform a sensitivity analysis based on the sample size, methodological quality, and missing data to obtain stable and reliable results.

Country(ies) involved: China.

Keywords: meta-analysis; prickingbloodletting cupping therapy; plaque psoriasis; systematic review.

Contributions of each author:

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