INPLASY PROTOCOL

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Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None.

Autologous blood or autologous serum acupoint injection therapy for Psoriasis Vulgaris: a protocol for a systematic review and meta-analysis

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Review question / Objective: **Psoriasis Vulgaris (PV) is a refractory and relapsing skin disease that affects the physical and mental health of patients and leads to poor quality of life. Current conventional systemic therapy shows a large side effect, can not be used for a long time, easy to relapse after drug withdrawal, long-term efficacy is poor. At present, traditional Chinese medicine treatment of PV effective, can alleviate symptoms, improve the quality of life, stabilize the condition, prolong the remission period. Whereas, there is no related systematic review and meta-analysis. Thus, we intend to conduct a systematic review and meta-analysis to testify autologous blood or autologous serum acupoint injection therapy for Psoriasis Vulgaris.**
Rationale: **Our systematic review will search all randomized controlled trials (RCTs) for autologous blood therapy of PV, electronically and manually, regardless of publication status and language, until March 19, 2020. Databases include PubMed, EMBASE, Web of Science, Cochrane Controlled Trials Register (CENTRAL), China National Knowledge Infrastructure (CNKI), China Biomedical Literature Database (CBM), Chinese Science Journal Database (VIP Database) and Wanfang database. Other sources, including reference lists of identified publications and meeting.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 April 2020 and was last updated on 10 April 2020 (registration number INPLASY202040052).

INTRODUCTION

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Condition being studied: Psoriasis Vulgaris (PV) is an immune-mediated polygenic hereditary dermatosis, which can be induced by many environmental factors. The typical clinical manifestation of psoriasis is squamous erythema or plaque, which is localized or widely distributed. This dermatosis damage can affect the whole body's skin, even accompanied by nail, joint lesions, repeated attacks difficult to heal, seriously affecting the physical and mental health of patients and quality of life. Due to the lack of specific therapeutic drugs, this disease has been one of the key research and prevention of diseases in the field of dermatology.

Rationale: Our systematic review will search all randomized controlled trials (RCTs) for autologous blood therapy of PV, electronically and manually, regardless of publication status and language, until March 19, 2020. Databases include PubMed, EMBASE, Web of Science, Cochrane Controlled Trials Register (CENTRAL), China National Knowledge Infrastructure (CNKI), China Biomedical Literature Database (CBM), Chinese Science Journal Database (VIP Database) and Wanfang database. Other sources, including reference lists of identified publications and meeting.

METHODS

Participant or population: The patient must be at least 18 years of and less than or equal to 65 years of age. Gender is not restricted. The stage or severity of the disease is not limited. Psoriasis must be diagnosed according to at least 1 internationally or nationally authorized diagnostic criterion. The international standard refers to the diagnostic criteria for psoriasis in the "Cecil Textbook of Medicine." Domestic standard refers to the diagnostic criteria for psoriasis in "Skins and Venereology," "Clinical Dermatology," or "Integrated Chinese and Western Medicine Skin Dermatology." The groups were well balanced when they were enrolled.

Intervention: The intervention group will use AB or AS acupoint injection therapy, while the control group adopts the placebo, drugs (modern medicine or traditional Chinese medicine (TCM)), other TCM therapies such as acupuncture, cupping and so on, or other active treatments, no treatment, diet and exercise therapy. The intervention group includes either a single AB or AS acupoint injection therapy or a combination of AB or AS acupoint injection therapy and main therapies (traditional systemic therapy, biologics, topical therapy, phototherapy, photochemotherapy, and TCM). It does not include the combination of AB or AS acupoint injection therapy with different types of TCM adjuvant therapy (such as acupuncture and moxibustion, TCM decoction, etc).

Comparator: A comparison of the following processing will be performed: 1. Autologous blood therapy is compared with non-autologous blood therapy. 2. Autologous blood therapy as compared to placebo or pseudo-autologous blood therapy. 3. Autologous blood therapy compared to other active therapies. 4. Autologous blood therapy is compared with the same active treatment except for active treatment.

Study designs to be included: The purpose of this systematic review is to comprehensively collect high-quality randomized controlled trials (RCTs), analyze and summarize the evidence.

Eligibility criteria: There will be no restrictions on the length of treatment and duration of follow-up. This systematic review will include high-quality RCTs in

English or Chinese that evaluated the therapeutic effect and safety of AB or AS acupoint injection therapy for PV. Without any date of dissemination or restriction of publication type. To RCTs, it should report adequate randomization methods, eligible diagnosis, eligible outcome measurement, and statistical methods description. Blinding will not be a part of the inclusion criteria because of the particularity of acupuncture manipulation. We will exclude the following types of studies: controlled (non-randomized) clinical trials, case reports, observational study, retrospective studies, animal mechanism studies, self-controlled, random crossover studies.

Information sources: The systematic review will search all randomized controlled trials (RCTs) by searching the following database: PubMed, EMBASE, Web of Science, Cochrane Controlled Trials Register (CENTRAL), China National Knowledge Infrastructure (CNKI), China Biomedical Literature Database (CBM), Chinese Science Journal Database (VIP Database) and Wanfang database with a language limitation of English and Chinese until March 2020. In addition, The related reference lists of identified publications, meeting minutes, gray literature, and unpublished literature for eligible studies which will be searched by us.

Main outcome(s): Measurements were based on the psoriasis area and severity index (PASI) score.

Additional outcome(s): 1) Quality of life measured by a specific scale. Available validated scales are the Dermatology Life Quality Index (DLQI), Skindex, Psoriasis Disability Index (PDI), or Psoriasis Symptom Inventory (PSI). 2) Itching score. 3) The proportions of participants with adverse effects (AE).

Data management: Before data extraction, a standard data extraction form containing specified outcomes will be created according to the inclusion. Two reviewers (QYW and ML) will extract data independently from each trial: article general information, participants' characteristics (such as age, sex, race, disease history), number of participants on each group, intervention measure of trial and control group, outcomes measures. Any disagreements will be resolved through discussion or consultation between the 2 reviewers if necessary, final determination from a third reviewer (PSH) will be sought. When certain dates don't be provided in the paper, we will contact the original author for the needed information.

Quality assessment / Risk of bias analysis: The authors (ML and QYW) will use the Cochrane Collaboration's bias risk assessment tool to assess the bias risk of all included studies. We will assess the risk of bias in the following areas: random sequence generation, concealment of allocation sequences, blindness of participants and staff and their result evaluators, incomplete outcome data, selective outcome reports, and other sources of bias. This review will use L, U, and H as the key to these assessments, where L (low) indicates a lower risk of bias, U (unclear) indicates an uncertain risk of bias, and H (high) indicates a higher risk of bias. All reviewers will resolve their differences through discussions. The information contained in the study on the risk of biased assessments will be summarized in a tabular format with a critical discussion of results and impacts. If the information is unclear, we will try to contact the author. For republished articles, we only select the original text.

Strategy of data synthesis: Data analysis and quantitative data synthesis will be performed using RevMan V.5.3. For continuous data, if there is no heterogeneity, we will use mean difference (MD) or standard MD (SMD) to measure the therapeutic effect of 95% CIs. If significant heterogeneity is found, a random-effects model will be used. For the two-category data, we will use the 95% CIs hazard ratio (RR) for analysis. We will include data from parallel-group design studies for meta-analysis. Only the first phase of the data will be included in the random crossover trial. In these trials, participants were randomly divided into two intervention

groups and individual measurements for each outcome of each participant were collected and analyzed. The result will be expressed as the RR of the binary data and the SMD of the continuous data. If the I^2 test is less than 50%, a fixed-effect model is used for data synthesis. If the I^2 test is between 50% and 75%, a random-effects model is used for data synthesis. If the I^2 test is higher than 75%, we will investigate the possible causes from a clinical and methodological perspective and provide a descriptive analysis or a subgroup analysis.

Subgroup analysis: There is no pre-subgroup plan for this project. When there are significant differences, we will carry out subgroup analysis according to the control group intervention measures and different results.

Sensibility analysis: When there are enough studies, we will conduct sensitivity analysis of the main results according to the sample size, heterogeneous quality and statistical model (random or fixed effect model) to explore the robustness of the conclusions. Sensitivity analysis will be conducted by removing low-quality studies. If heterogeneity still exists after subgroup analysis, a meta-analysis will be performed again after excluding low-quality tests according to STRICTA checklist. The results of these meta-analyses will be compared and discussed in terms of their sample size, the strength of the evidence, and their impact on the size of the merger effect. However, if there is a high risk of bias in all included studies, we will not conduct sensitivity analysis.

Language: English.

Country(ies) involved: China.

Keywords: Autologous blood; autologous serum; psoriasis vulgaris; injection; protocol; systematic review.

Contributions of each author:
Author 1 - Author 1 drafted the manuscript.
Author 2 - The author provided statistical expertise.
Author 3 - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 4 - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 5 - The author read, provided feedback and approved the final manuscript.