INPLASY PROTOCOL

To cite: Zou et al. Moxibustion therapy for treating Psoriasis vulgaris：a protocol for systematic review and meta-analysis. Inplasy protocol 202120008. doi: 10.37766/inplasy2021.2.0008

Received: 02 February 2021

Published: 02 February 2021

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Support: **NO:2018YFC1705303.**

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

Conflicts of interest:
None declared.

Moxibustion therapy for treating Psoriasis vulgaris：a protocol for systematic review and meta-analysis

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Review question / Objective: **Psoriasis vulgaris (PV) is a recurrent chronic inflammatory skin disease. In recent years, with the fast-paced life and work and unhealthy diet, the incidence has increased year by year, which has seriously affected the quality of life of patients. At present, Moxibustion therapy has been widely used in the treatment of PV. However, due to the lack of clinical systematic evaluation and evidence-based medicine evidence. Therefore, this study will provide high quality evidence based medicine to evaluate the effectiveness and safety of moxibustion for PV.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 February 2021 and was last updated on 02 February 2021 (registration number INPLASY202120008).

INTRODUCTION

Review question / Objective: **Psoriasis vulgaris (PV) is a recurrent chronic inflammatory skin disease. In recent years, with the fast-paced life and work and unhealthy diet, the incidence has increased year by year, which has seriously affected the quality of life of patients. At present, Moxibustion therapy has been widely used in the treatment of PV. However, due to the lack of clinical systematic evaluation and evidence-based medicine evidence. Therefore, this study will provide high**

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quality evidence based medicine to evaluate the effectiveness and safety of moxibustion for PV.

Condition being studied: Psoriasis is a recurrent chronic inflammatory skin disease. Among the four clinical types, psoriasis vulgaris(PV) has the highest incidence of 85.1%. It is characterized by scaly redness or patches, and the rash affects all parts of the body. In recent years, with the fast-paced life and work and unhealthy diet, the incidence has increased year by year, which has seriously affected the quality of life and work efficiency of patients. Research shows that 0.47% of people in China are still affected. At present, Western medicine does not have a good radical cure plan, and it has become one of the difficulties in medical treatment at home and abroad. It is worthwhile for clinical medical staff to continue to study and explore treatment methods with better curative effects. As one of the traditional Chinese acupuncture and moxibustion therapies, moxibustion therapy for psoriasis vulgaris has become a hot spot in clinical research in recent years, but due to the lack of clinical systematic evaluation and evidence-based medicine evidence.Therefore, a randomized controlled trial of moxibustion therapy for psoriasis vulgaris is analyzed based on systematic evaluation to explore the efficacy and safety of moxibustion therapy.

METHODS

Search strategy: The following strategy was used retrieve data from the PubMed, Embase, the Cochrane Library: (Psoriasis OR Plaque Psoriasis OR psoriasis vulgaris OR BaiBi) AND (Moxibustion OR Moxibustion therapy). Any clinical randomised controlled trials (RCTs) related to Moxibustion therapy for psoriasis vulgaris will be taken into. The search will be restricted to human subjects.

Participant or population: Participants with physician-diagnosed PV will be included in this review. There will be no restriction on age, gender, ethnic group, the intensity or duration of symptoms .Those patients combined with other basic diseases will be excluded.

Intervention: Different types of moxibustion therapy will be included (e.g.indirect moxibustion, direct moxibustion, heat-sensitive moxi-bustion, etc). Moxibustion as the main part of the combined therapy will also be included.There will be no limited to the moxibustion materials or frequency of intervention or acupuncture points.

Comparator: The control group could gain guideline-recommended conventional treatment and a placebo or Other combination therapies and so on.

Study designs to be included: All RCTs of moxibustion treatment for PV will be included, regardless of whether blind method is used. Other types of studies such as non-RCTs will be excluded.

Eligibility criteria: We will include RCT to evaluate the effectiveness and safety of moxibustion therapy for PV. The inclusion criteria are as follows: 1. The type of study is a randomized controlled trial.2. The subjects of this study were patients with clinically confirmed PV. The exclusion criteria are as follows: 1.Medical review, medical record reports, animal experimental research;2. Select the latest one among the repeated publications; 3.Women in a special period (pregnancy or lactation); 4.Joint psoriasis, Pustular psoriasis, Erythroderma psoriasis; 5.Documents whose full text cannot be obtained from various sources; 6.Combined with other serious organic diseases or mental diseases.

Information sources: The following electronic databases will be searched: PubMed, Embase, Cochrane Library, China National Knowledge Infrastructure, WangFang Database, Chinese Science Journal Database, Chinese Biomedical Literature Database from the inception to February, 2021 without any language limitation. What's more, the grey literature and the references of all included literature will also be retrieved manually.Any clinical

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randomised controlled trials (RCTs) related to Moxibustion therapy for PV will be taken into.

Main outcome(s): The major outcomes included the following: 1.clinical effect (recovery rate, and total effective rate); 2.Psoriasis area and severity index (PASI score): the patient's condition score was based on PASI score (Psoriasis area and severity index), including skin lesion area score and skin lesion severity score.

Additional outcome(s): The secondary outcomes included the following: 1. Itchy (VAS score); 2.Dermatology Quality Life Index (DLQI score); 3.Symptom score according to the evaluation standard of Chinese medicine; 4.Side effects and adverse events.

Data management: The data will be extracted independently in the form of excel by the 2 researchers, then cross-check and verify each other. Any disagreement will be resolved by discussion with a third reviewer. The extracted data mainly includes the following information: literature information (first author, publication year, study area), research methods, participant characteristics, sample size, intervention(s), outcome(s), adverse event(s), and other relevant characteristics.

Quality assessment / Risk of bias analysis: The Cochrane risk-of-bias tool will be used to evaluate the methodological quality of each included trial, and each RCT will be assessed for the following characteristics: (1) selection bias; (2) performance bias; (3) detection bias; (4) attrition bias; (5) reporting bias. (6) other bias. The terms 'Low', 'Unclear', and 'High' was referred to low, uncertain, and high risks of bias, respectively.The quality evaluation results included in the test were cross-examined by two evaluators.If necessary, we will contact the corresponding author to clarify issues. Any disagreements will be resolved through discussion or consultation with the third reviewer.

Strategy of data synthesis: We will use RevMan software (Version5.3, Copenhagen: Nordic Cochrane Center, Cochrane Collaboration, 2014) for meta-analysis. Mean difference (MD) or standard mean difference (SMD) with 95% confidence intervals (CIs) were used as the effect measure for continuous data and the odds ratio (OR) with 95%CIs were used for dichotomous outcomes.When P>0.1 andI2 50%, the random effects model will be used for merger the analysis. If the P value and the I2 value are inconsistent with each other, the I2 value will be used as the difference Qualitative criteria. Descriptive analysis or sensitivity analysis will be performed when there is significant clinical heterogeneity between studies.

Subgroup analysis: If the heterogeneity test results between the studies are large, we will try to conduct a subgroup analysis based on the age, gender, intervention measures, and treatment time of the participants.

Sensitivity analysis: Sensitivity analysis is mainly to judge the stability and reliability of the research results. If the heterogeneity between the studies is large, the sensitivity analysis is carried out according to the sample size, methodological quality, and data loss to obtain a stable Reliable results.

Language: English.

Country(ies) involved: China.

Keywords: moxibustion; Psoriasis vulgaris; protocol; systematic review.

Contributions of each author:
Author 1 - Jiahua Zou - drafted the manuscript.
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