INPLASY PROTOCOL

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

**Conflicts of interest:**
**None declared.**

# Fire needle therapy combined with 30% supramolecular salicylic acid for mild-to-moderate acne vulgaris: A protocol for systematic review and meta-analysis

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**Review question / Objective:** **The purpose of this study is to assess the clinical efficacy and safety of fire needle therapy combined with 30% supramolecular salicylic acid for mild-to-moderate acne vulgaris.**
**Condition being studied:** **Acne vulgaris (AV) is a common inflammatory skin disease with substantial cutaneous and psychologic disease burden. Fire needle therapy and 30% supramolecular salicylic acid are both alternative treatment options for AV. In recent years, some articles have reported good clinical efficacy of fire needle therapy combined with 30% supramolecular salicylic acid for mild-to-moderate AV. However, there is no evidence-based medical proof to prove it. Therefore, we provide a protocol to evaluate the effects and safety of fire needle therapy combined with 30% supramolecular salicylic acid for mild-to-moderate AV.**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 September 2021 and was last updated on 12 September 2021 (registration number INPLASY202190033).

## INTRODUCTION

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therapy and 30% supramolecular salicylic acid are both alternative treatment options for AV. In recent years, some articles have reported good clinical efficacy of fire needle therapy combined with 30% supramolecular salicylic acid for mild-to-moderate AV. However, there is no evidence-based medical proof to prove it. Therefore, we provide a protocol to evaluate the effects and safety of fire needle therapy combined with 30% supramolecular salicylic acid for mild-to-moderate AV.

## METHODS

**Participant or population:** Participants diagnosed with acne vulgaris. There is no restriction with respect to age, gender, race, nationality, and educational background.

**Intervention:** Fire needle therapy combined with 30% supramolecular salicylic acid.

**Comparator:** The same supramolecular salicylic acid as the treatment group.

**Study designs to be included:** Randomized controlled trials.

**Eligibility criteria:** Only RCTs of fire needle therapy combined with 30% supramolecular salicylic acid for mild-to-moderate AV will be included. The languages of included articles will be limited to English or Chinese.If trials meet any of the following conditions, it will be excluded: 1. Non-RCTs, quasi-RCTs, retrospective studies, case reports, animal trials and reviews; 2. Lack of fire needle therapy in the treatment or fire needle therapy use in the control group; 3. The treatment group use other TCM measures, such as scraping, external application of herbal medicines and so on; 4. Duplicated publications, the data cannot be synthesized, and the full text cannot be obtained.

**Information sources:** Three English electronic databases including the Cochrane Library, PubMed, EMBASE and four Chinese electronic databases including Chinese National Knowledge Infrastructure Database, Chinese Biomedical Literature Database, Chinese Science and Technique Journals Database, and the Wan-fang Database will be searched from the database inception to September 2021. There are no language or publication restrictions. Meanwhile, we will also pay attention to the reference lists of included studies and gray literature.

**Main outcome(s):** The primary outcome is the effective rate in the treatment and control groups. The skin lesions of patients are evaluated before and after treatment. Responses to interventions are classified as cured, markedly effective, effective, and ineffective.

**Additional outcome(s):** Adverse reactions.

**Quality assessment / Risk of bias analysis:** The 2 investigators will independently evaluate the risk of bias in trials based on the Cochrane Handbook for Systematic Reviews of interventions. The items as follow will be assessed: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other sources of bias. Each domain is classified as low, unclear, or high risk of bias. A third party will be in charge of resolving the discrepancies in the interpretation.

**Strategy of data synthesis:** RevMan 5.3 software will be adapted to perform a meta-analysis. The relative risk will be used to analyze the dichotomous outcomes. For continuous outcomes, we will use the mean difference. The uncertainty is expressed with 95% confidence intervals, and the heterogeneity is measured using the I2 statistic. When I2 < 50%, a fixed-effects model will be used. Otherwise, a random-effects model will be selected to analyze. If meta-analysis is not available, we will perform descriptive analysis.

**Subgroup analysis:** Subgroup analyses based on frequency of fire needle therapy

in the treatment group, duration of treatment will be conducted.

**Sensitivity analysis:** Sensitivity analysis including changing the effect model, statistical methods and removing high-risk bias studies will be performed to evaluate the credibility of the synthetic outcomes.

**Country(ies) involved:** China.

**Keywords:** fire needle, salicylic acid, mild-to-moderate acne vulgaris, meta-analysis, protocol, systematic review.

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