INPLASY PROTOCOL

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Corresponding author:
Hao Ping-sheng

hpswl@126.com

Author Affiliation:
Hospital of Chengdu University of TCM

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30% Supramolecular Salicylic Acid in the Treatment of Mild to Moderate Acne Vulgaris on the Face: A Systematic Review and Meta-analysis of Randomised Controlled Trials

Mao, L[1]; Jingjing, D[2]; Qiuyue, W[3]; Linyue, W[4]; Yuting, L[5]; Pingsheng, H[6].

Review question / Objective: **On the basis of conventional treatment, is it safe and effective to add 30% supramolecular salicylic acid to patients with mild to moderate acne vulgaris.**
Condition being studied: **Acne vulgaris is a common chronic inflammatory skin disease of the hair follicle and sebaceous glands, which occurs frequently in adolescence. Although the disease has a certain tendency to heal itself, its course is longer. The skin lesions of this disease often occur on the face. In severe cases, scars and facial melanin deposits can form, which not only affects the appearance, but also has a certain impact on the patient's emotional and mental health.Supramoleic salicylic acid is a new type of skin resurfacing agent. Its principle is to introduce supermolecules into salicylic acid to form a complex, which can improve skin function and improve skin appearance through chemical exfoliation.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 April 2020 and was last updated on 17 April 2020 (registration number INPLASY202040109.

INTRODUCTION

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Rationale: In this study, the meta-analysis was used to statistically process the clinical literature to clarify the clinical efficacy of 30% supramolecular salicylic acid therapy for mild to moderate acne vulgaris, and to further explore its clinical regularity to provide reference and help for clinical treatment and related research.

METHODS

Search strategy: Our systematic review will search all randomized controlled trials (RCTs) for 30% supramolecular salicylic acid therapy of Mild to moderate acne vulgaris, electronically and manually, regardless of publication status and language, until April 15, 2020. Electronic searches were performed with the following search terms: ("30% supramolecular salicylic acid " OR "mild to moderate acne vulgaris").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 Wan Party database. Other sources, including reference lists of identified publications and meeting minutes, will also be searched. Manually search for grey literature, including unpublished conference articles.

Participant or population: Regardless of gender, age, ethnicity, education and economic status, patients with mild to moderate acne vulgaris who meet the following diagnostic criteria (e.g, JAD/AAD/EDF guidelines, guidelines for the diagnosis and treatment of Chinese acne vulgaris).

Intervention: The intervention group was mainly treated with 30% supramolecular salicylic acid.

Comparator: A comparison of the following processing will be performed: 1. The 30% supramolecular salicylic acid treatment was compared with the fruit acid treatment. 2. Compare 30% supramolecular salicylic acid therapy with other topical ointment therapy. 3. Compare 30% supramolecular salicylic acid therapy with oral antibiotic therapy. 4. Compare 30% supramolecular salicylic acid therapy with TCM fire needle therapy. 5 Compare 30% of supramolecular salicylic acid therapy with laser therapy.6.

Study designs to be included: We will include in the randomized controlled trial (RCT) without the limitations of language and publicity.

Eligibility criteria: Only RCTs (except QuasiRCTs and cluster RCTs) will be included. Exclusion criteria:Animal mechanism studies and nonrandomised clinical trials,Duplicate publications, published publications are abstracts, and the full texts are still unavailable after contacting the authors. The data in the literatures are incomplete or have obvious errors. The intervention group is the literatures of30% supramolecular salicylic acid combined medicine (Chinese or Western Medicine), articles in which the 30% supramolecular salicylic acid was not the main intervention in the intervention group.The language and time of publication will not be restricted.

Information sources: 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 Wan Party database. Other sources, including reference lists of identified publications and meeting minutes, will also be searched. Manually search for grey literature, including unpublished conference articles.

Main outcome(s): Effective rate of treatment: the treatment time of the two groups of patients is 30 days. After the treatment, the treatment effect of the two groups of patients is evaluated. The effect is remarkable: acne, skin lesions, pustules and other conditions of the patients basically disappear after treatment; Effective: The above three symptoms are obviously relieved; Ineffective: After treatment, the above symptoms are not relieved or even aggravated. Therapeutic effective rate = (marked effect+effective number)/total number of cases ×100%.

Additional outcome(s): 1. Skin lesions: Before and after treatment, the camera was used to keep positive and lateral photographs of the patient's bilateral faces. Professional dermatologists recorded the number of acne, pustules and papules in a field of vision, and compared them before and after treatment and between groups. 2.incidence of adverse reactions: follow-up, follow-up and other methods were used to observe and record various adverse reactions, such as dryness, skin pruritus, peeling, etc. occurred during 30 days of treatment between the two groups, and inter-group treatment was carried out contrast.

Data management: Prior to the literature search, the research experience will be trained to ensure consistency in the evaluation of this study. During the screening of the literature, we will use the EndNote X9 document management software.According to the PRISMA flow chart, two researchers(M.L and JJD)will strictly follow the inclusion criteria, independently screen all retrieved studies, read the titles, abstracts and keywords of the literature, and determine which trials meet the inclusion criteria, while obtaining the following information: general information, participation Methods, interventions, outcomes, outcomes, adverse events, conflicts of interest, ethical recognition, and other information. We will obtain all the research-related full text for further evaluation. Any disagreement over data relevancy was settled by a third reviewer.

Quality assessment / Risk of bias analysis: The evaluation was performed according to the bias risk assessment tool provided by Cochrane Handbook 5.2.0, and Rev Man 5.3.5 software was used to generate the bias risk map. A third reviewer was consulted if uncertainties occurred.We will assess the risk of bias in the following areas: sequence generation, assignment sequence hiding, blindness of participants and staff, and result evaluators, incomplete outcome data, selective outcome reporting, and other sources of bias. This review uses L, U, and H as the key to these assessments, where L (low) indicates a lower risk of bias, U (unclear) indicates that the risk of bias is uncertain, and H (high) indicates a higher risk of bias. Information on the risk of biased assessments included in the study is summarized in tabular form and the results and impacts are critically discussed. If the information is ambiguous, we will try to contact the author. For repeated publications, we only select the original text.

Strategy of data synthesis: Data analysis and quantitative data synthesis will be performed using RevMan V.5.2. By convention, for continuous variables, we adopt the mean difference (MD)with 95% CIs to calculate the effect size. In addition, related risks (RRs) with 95% CIs will be applicable when it comes to dichotomous data.If significant heterogeneity is found, a random effects model will be used. We will use random-effect model (REM) for meta-analysis in this review according to research recommendations. Statistical heterogeneity will be assessed by X^2 and I2 statistical tests. Where p value ≥0.1and I2 ≤50%, there is no obvious statistical heterogeneity among the studies. On the contrary, where p value 50% indicates a considerable heterogeneity. Meta-analysis will be performed when the statistical heterogeneity is acceptable (p value ≥0.1and I2 ≤50%), otherwise, subgroup analysis will be applied to explore the

influence of potential factors on the outcome measures.

Subgroup analysis: If the heterogeneity test indicates that the heterogeneity is high, it is not suitable to directly combine the effect amounts for meta-analysis. The random effect model and sensitivity analysis are used to test the reliability of the results, analyze the sources of heterogeneity, and We will establish subgroup according to the different comparisons, or other factors that may affect outcomes, such as age, interval and duration of treatment, diagnostic criteria, or quality of studies, etc.

Sensibility analysis: Sensitivity analysis will be performed to evaluate the quality and stability of meta-analysis results. One analysis solution is to incorporate with random-effect model. On the other hand, we can exclude each included study one by one and re-analysis these dates to pinpoint the trial that induced distinction and finally eliminate it from eligible studies.

Language: The language is limited to English and Chinese.

Country(ies) involved: China.

Keywords: 30% supramolecular salicylic acid ; mild to moderate acne vulgaris; Randomized controlled trials; Systematic review; Meta-analysis.

Contributions of each author:
Author 1 - The author wrote the original draft and contributed to conceptualization, methodology and software.
Author 2 - The author provided statistical expertise.
Author 3 - The author is responsible for data curation and investigation.
Author 4 - The author is responsible for data curation and investigation.
Author 5 - The author is responsible for data curation and investigation.
Author 6 - The author is responsible for supervision and writing of the review.