INPLASY PROTOCOL

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Conflicts of interest:
None.

Moxibustion therapy for chronic spontaneous urticaria: a protocol for systematic review and meta-analysis

Shen, S[1]; Wang, M[2]; Dong, J[3].

Review question / Objective: **In clinical, chronic spontaneous urticaria is a very common disease. Chronic spontaneous urticaria is marked by severe itching, often recurrent, and the course is often long and unpredictable. The pathogenesis of chronic spontaneous urticaria is complex, and it is often difficult to find a clear cause. Therefore, it is difficult to carry out targeted treatment of the cause, and only symptomatic treatment is currently available. However, sometimes symptomatic treatment such as antihistamines cannot completely control the symptoms of chronic spontaneous urticaria, which seriously affects the quality of life of patients. Therefore, other effective and safe treatments are needed. Moxibustion therapy is a complementary and alternative medicine technique with a long history in China, and it is effective in treating chronic spontaneous urticaria. It can relieve symptoms, stabilize the condition, prolong the remission period, and finally improve quality of life. In view of there is no relevant systematic reviews and meta-analysis. Therefore, we intend to conduct a systematic review and meta-analysis to prove the effect of moxibustion therapy for chronic spontaneous urticaria.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 October 2020 and was last updated on 13 October 2020 (registration number INPLASY2020100045).

INTRODUCTION

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symptomatic treatment is currently available. However, sometimes symptomatic treatment such as antihistamines cannot completely control the symptoms of chronic spontaneous urticaria, which seriously affects the quality of life of patients. Therefore, other effective and safe treatments are needed. Moxibustion therapy is a complementary and alternative medicine technique with a long history in China, and it is effective in treating chronic spontaneous urticaria. It can relieve symptoms, stabilize the condition, prolong the remission period, and finally improve quality of life. In view of there is no relevant systematic reviews and meta-analysis. Therefore, we intend to conduct a systematic review and meta-analysis to prove the effect of moxibustion therapy for chronic spontaneous urticaria.

Condition being studied: Urticaria is a localized edema reaction caused by the expansion of small blood vessels in the skin and mucous membranes and increased permeability with the activation of mast cells as the core. It is often accompanied by wind masses of varying sizes, itching, and angioedema. The course of chronic urticaria is more than 6 weeks. There are different types of chronic urticaria, usually divided into spontaneous and inducible urticaria. Among them, chronic spontaneous urticaria is the most common clinical type of chronic urticaria. Chronic spontaneous urticaria has significant itching and often recurrence, which seriously affects the quality of life of patients. However, sometimes primary therapies such as antihistamines cannot completely control the symptoms of chronic spontaneous urticaria, so other effective and safe treatments are needed.

METHODS

Participant or population: The intervention group must use moxibustion therapy, including thunder fire moxibustion, taiyi miraculous moxa roll, suspended moxibustion, mild moxibustion, needle warming moxibustion. The acupoints used must according to traditional Chinese medicine nomenclature. Moxibustion therapy as the only treatment should be included. Moxibustion therapy combined with other active therapy should be excluded, besides a combination of moxibustion therapy and other active therapies, while the control group used the same active therapy.

Intervention: The intervention group must use moxibustion therapy, including needle warming moxibustion, thunder fire moxibustion, mild moxibustion, taiyi moxibustion, and suspended moxibustion. The acupoints used must according to traditional Chinese medicine nomenclature.

Comparator: The control interventions of the following processing will be included: 1. Moxibustion therapy is compared with other active therapies. 2. Moxibustion therapy is compared with sham therapies or placebo. 3. Moxibustion therapy in addition to active therapy compared with the same active therapy. 4. No treatment in control group. Any treatment related to moxibustion therapy in control group will be excluded.

Study designs to be included: The purpose of this systematic review is to evaluate the efficacy of moxibustion therapy in the treatment of chronic spontaneous urticaria. This paper will comprehensively collect and include only high-quality randomized controlled trials (RCTs).

Eligibility criteria: The publications will be included with language limitation of English and Chinese, while other languages will be excluded. There will be no restrictions on the blind method. In additional, follow-up will also not be restricted. The papers try various methods (e.g. change the database, contacting the author), but still unable to find the full article, will be excluded. Controlled (non-randomized) clinical trials, cohort studies, non-human studies, non-RCTs, case reports, observational study, random crossover studies, retrospective studies, single arm studies and reviews will be excluded.

Information sources: Regarding RCTs be included, the following databases will be

searched: PubMed, Web of science, EMBASE.com and Cochrane library, China National Knowledge Infrastructure (CNKI), Chinese Academic Journal Database (WanFang Data), Chinese Science Journal Database (VIP Database) and China Biomedical Literature Database (CBM). The publications reported in Chinese and English will be included, until June 30th, 2020. In addition, references will be manual searched for relevant studies to find studies that may qualify.

Main outcome(s): The main outcome is based on the Urticarial activity score (UAS) and the European MILOR rating scale.

Additional outcome(s): The additional outcomes include: 1) Assessment of efficacy: Symptom score reduce index and Global symptom improvement, 2) Assessment of quality of life: Available validated scales are the Dermatology Life Quality Index, 3) Assessment of Objective index: IgE.

Quality assessment / Risk of bias analysis: All of the methodological qualities of the trials will be inspected and evaluated by two authors (Shen and Wang) independently. If the relevant data, such as blinding methods or random methods, is not published in the paper, we will try to contact the original author by email or telephone to obtain the information. The two authors will use the Cochrane Collaboration's bias risk assessment tool to assess the bias risk of all included studies. The following areas will be assessed the risk of bias: Random sequence generation, assignment sequence concealment, blinding of trial personnel and participants, blinding of outcome assessors, incomplete outcome data, selective outcome reporting, and other biases. In case of disagreement between the two reviewers, they will consult a third clinically experienced reviewer (Dong).

Strategy of data synthesis: The Review Manager 5.3 will be used for statistical analysis. Effect model: Choose the fixed or random effect model according to the heterogeneity test results of the study. If $P>0.1$ and $I2\leq50\%$, the heterogeneity is considered acceptable, and the fixed effect model is used; if $P<0.1$ and I2 If $\geq50\%$, the heterogeneity is considered to be out of the acceptable range, and the random effects model is used to analyze the reasons for the heterogeneity. Effect scale index: Select according to the type of data, if the data is binary data, use odds ratio (OR); if the data is continuous data, use standardized mean difference (SMD). Both calculate the 5% confidence interval (CI), if $P\leq0.05$, the difference is considered statistically significant. If more than 8 studies are included, draw a funnel chart to observe whether there is publication bias.

Subgroup analysis: There is no presubgroup plan. If feasible, we will conduct subgroup analysis based on control interventions, different outcome, etc.

Sensibility analysis: When there are enough researches, we will conduct sensitivity analysis of the main results to explore the reliability of the conclusions. If the sensitivity analysis does not substantially change the results, the results are credible; if the sensitivity analysis yields different conclusions, suggesting that there are potentially important factors that affect the effects of interventions. It indicates should be cautious when interpreting the results and drawing conclusions, and need to be clear the source of the dispute.

Country(ies) involved: China.

Keywords: moxibustion therapy; chronic spontaneous urticaria; protocol; systematic review.

Contributions of each author:
Author 1 - Sijia Shen.
Author 2 - Meiling Wang.
Author 3 - Jingcheng Dong.