INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Therapeutic effect of acupuncture combined montelukast sodium on cough variant asthma in children: A protocol for systematic review and meta-analysis

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Review question / Objective: **Cough variant asthma in children is a special type of asthma. Although there are many effective cases of combined acupuncture and western medicine in the clinical treatment of this kind of children, there is no standardized acupuncture combined with western medicine to evaluate the curative effect. Therefore, combined with existing reports, a systematic review and meta-analysis of acupuncture combined with montelukast sodium in the treatment of cough variant asthma in children were carried out to obtain conclusive results.**
Condition being studied: **Therapeutic effect of acupuncture combined montelukast sodium on cough variant asthma in children. This study will be conducted by a professional team consisting of doctors and masters, and reviewed by professors to ensure accuracy and completeness. The research has entered the preliminary stage and will be supported by the project funds of the National Administration of Traditional Chinese Medicine to ensure its completion.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 November 2021 and was last updated on 03 November 2021 (registration number INPLASY2021110006).

INTRODUCTION

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Condition being studied: Therapeutic effect of acupuncture combined montelukast sodium on cough variant asthma in children. This study will be conducted by a professional team consisting of doctors and masters, and reviewed by professors to ensure accuracy and completeness. The research has entered the preliminary stage and will be supported by the project funds of the National Administration of Traditional Chinese Medicine to ensure its completion.

METHODS

Participant or population: Type of participants. Studies on adult patients, 18 years old or below, who were diagnosed as CVA will be included in this study. No limitations of location, educational background, and gender will be imposed.

Intervention: Type of interventions. Any forms of AM therapy used to treat patients with CVA will be included in the experimental group. Any other treatments, but not AM, used to manage participants with CVA will be entered in the control group.

Comparator: Comparing the clinical efficacy of the two groups, the criteria for judging: the symptom disappeared after one week of treatment and no recurrence within 3 months is markedly effective; after the treatment, the cough symptoms of the child are alleviated, but occasionally it is effective as treatment; Later, the symptoms of the child did not disappear or even worsened to be invalid. The lung function indexes of the two groups before and after treatment were compared, including the forced end expiratory volume in the first second (FEV1) and the forced vital capacity (FVC). The improvement of clinical symptoms in the two groups was compared, including the duration of asthma, wheezing, and time to disappear cough. The inflammatory factor indexes before and after treatment were compared between the two groups, including C-reactive protein (CRP) and procalcitonin (PCT). Observe the occurrence of adverse reactions such as dizziness, headache, abdominal pain, nausea and vomiting in the 2groups.

Study designs to be included: 2.2.1. Type of studies. Any randomized controlled trials (RCTs) exploring the effectiveness and safety of AM for the treatment of patients with CVA will be included. We will not consider other studies, such as non-clinical trials, non-controlled trials, and non-RCTs.

Eligibility criteria: 2.2.1. Type of studies. Any randomized controlled trials (RCTs) exploring the effectiveness and safety of AM for the treatment of patients with CVA will be included. We will not consider other studies, such as non-clinical trials, non-controlled trials, and non-RCTs. 2.2.2. Type of participants. Studies on adult patients, 18 years old or below, who were diagnosed as CVA will be included in this study. No limitations of location, educational background, and gender will be imposed. 2.2.3. Type of interventions. Any forms of AM therapy used to treat patients with CVA will be included in the experimental group. Any other treatments, but not AM, used to manage participants with CVA will be entered in the control group. 2.2.4. Type of outcomes. Comparing the clinical efficacy of the two groups, the criteria for judging: the symptom disappeared after one week of treatment and no recurrence within 3 months is markedly effective; after the treatment, the cough symptoms of the child are alleviated, but occasionally it is effective as treatment; Later, the symptoms of the child did not disappear or even worsened to be invalid. The lung function indexes of the two groups before and after treatment were compared, including the forced end expiratory volume in the first second (FEV1) and the forced vital capacity (FVC). The improvement of clinical symptoms in the two groups was compared, including the duration of asthma, wheezing, and time to disappear cough. The inflammatory factor indexes before and after treatment were compared between the two groups, including C-reactive protein (CRP) and procalcitonin

(PCT). Observe the occurrence of adverse reactions such as dizziness.

Information sources: 2.3 Search strategy and analysis 2.3.1 Electronic searches The selection of the time for inclusion of the literature will be selected from the establishment of each database to October 30, 2021, by searching PubMed, Embase, Cochrane Library, Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database (VIP), PubMed, and other seven databases. Keywords include"acupuncture combined montelukast sodium, "、"Cough variant asthma, " and so on. Specific search terms in Table 1. 2.3.2 Data extraction and quality assessmen. Two authors will independently select the trials according to the inclusion criteria, and import into Endnote X9. Then remove duplicated or ineligible studies. Screen the titles, abstracts, and full texts of all literature to identify eligible studies. All essential data will be extracted using previously created data collection sheet by 2 independent authors. Discrepancies in data collection between 2 authors will be settled down through discussion with the help of another author. The following data will be extracted from each included research: the first author's surname, publication year, language of publication, study design, sample size, number of lesions, source of the subjects, instrument, "criterion standard, and diagnostic accuracy. The true positives, true negatives, false positives, and false negatives in the 4-fold (2 × 2) tables were also collected. Methodological quality was independently assessed by 2 researchers based on the quality assessment of studies of diagnostic accuracy studies (QUADAS) tool. The QUADAS criteria included 14 assessment items. Each of these items was scored as "yes" (2), "no" (0), or "unclear". The QUADAS score ranged from 0 to 28, and a score ≥22 indicated good quality. Any disagreements between 2 investigators will be solved through discussion or consultation by a 3rd investigator. 2.2.2. Type of participants. Studies on adult patients, 18 years old or below, who were diagnosed as CVA will be included in this study. No limitations of location, educational background, and gender will be imposed. 2.2.3. Type of interventions. Any forms of AM therapy used to treat patients with CVA will be included in the experimental group. Any other treatments, but not AM, used to manage participants with CVA will be entered in the control group.

Main outcome(s): Type of outcomes. Comparing the clinical efficacy of the two groups, the criteria for judging: the symptom disappeared after one week of treatment and no recurrence within 3 months is markedly effective; after the treatment, the cough symptoms of the child are alleviated, but occasionally it is effective as treatment; Later, the symptoms of the child did not disappear or even worsened to be invalid. The lung function indexes of the two groups before and after treatment were compared, including the forced end expiratory volume in the first second (FEV1) and the forced vital capacity (FVC). The improvement of clinical symptoms in the two groups was compared, including the duration of asthma, wheezing, and time to disappear cough. The inflammatory factor indexes before and after treatment were compared between the two groups, including C-reactive protein (CRP) and procalcitonin (PCT). Observe the occurrence of adverse reactions such as dizziness, headache, abdominal pain, nausea and vomiting in the 2 groups.

Quality assessment / Risk of bias analysis: Assessment of risk of bias. Two researchers will independently evaluate the risk and bias using the Cochrane collaboration's tool. These items included in this toll will be evaluated: random sequence generation, allocation concealment, the blinding method for patients, researchers and outcomes assessors, incomplete outcome data, and selective reports. The bias risk for every item will be classed as "low risk of bias," "high risk of bias," "unclear risk of bias."

Strategy of data synthesis: 2.3.6. Data synthesis.The STATA version 14. 0 (Stata Corp, College Station, TX) and Meta-Disc version 1. 4 (Universidad Complutense, Madrid, Spain) soft wares were used for meta-analysis. We calculated the pooled summary statistics for sensitivity, specificity, positive and negative likelihood ratio, and diagnostic odds ratio with their 95% confidence intervals. The summary receiver operating characteristic curve and corresponding area under the curve were obtained. The threshold effect was assessed using Spearman correlation coefficients. The Cochrans Q-statistic and I test were used to evaluate potential heterogeneity between studies. If significant heterogeneity was detected (Q test P < . 05 or I test >50%), a random-effects model or fixed-effects model was used.[12] We also performed subgroup and meta-regression analyses to investigate potential sources of heterogeneity. To evaluate the influence of single studies on the overall estimate, a sensitivity analysis was performed. We conducted Beggs funnel plots and Eggers linear regression tests to investigate publication bias.

Subgroup analysis: Subgroup analysis. When there is disagreement in the results, a subgroup analysis needs to be carried out for different reasons. Heterogeneity is mainly manifested in many aspects such as race, sex, age, drug formulations, different forms of intervention, treatment time, and drug dosages.

Sensitivity analysis: Sensitivity analysis. When there are sufficient studies, we will carry out sensitivity analysis to test the robustness of studies according to the quality of method, the sample size, and the selection of missing data. And the fluctuation of results will be observed.

Country(ies) involved: China.

Keywords: Montelukast sodium; cough variant asthma in children.

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