INPLASY PROTOCOL

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Corresponding author:
Haiju Sun

sunhaiju0411@qq.com

Author Affiliation:
The Third Clinical Medical College, Zhejiang Chinese Medical University

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Conflicts of interest:
None.

Effectiveness and Safety of Moxibustion for Asthma in Children: A Protocol for Systematic Review and Meta-Analysis of Randomized Controlled Trials

Sun, H[1]; Li, X[2]; Zhang, Y[3]; Lou, J[4]; Jiang, Y[5]; Fang, J[6].

Review question / Objective: **Whether moxibustion is effective and safe for asthma in children?**
Condition being studied: **Asthma is a common problem, particularly in children. In the United States, more than 22 million people suffer from asthma; nearly 6 million of them are children. About 14 million days of absence from school are caused by asthma. Even though the management of asthma in children has improved, hospitalization rates remain high. Conventional medicines, especially inhaled corticosteroids and short-acting β2-adrenoceptor agonists are effective treatments. However, the adverse effects of these drugs are considerable. For instance, inhaled corticosteroids can slow the growth of children of all ages. Therefore, some effective, low-risk, non-invasive treatments would be most welcome. In clinical practice, moxibustion therapy is widely used in the treatment of asthma and has achieved a certain therapeutic effect. It is found in clinical and experimental researches that moxibustion regulates the nervous system and immune system in both directions through body surface stimulation. But, the efficacy and safety of moxibustion for asthma in children need to be further evaluated.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 December 2020 and was last updated on 15 December 2020 (registration number INPLASY2020120083).

INTRODUCTION

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METHODS

Search strategy: The following six databases, three each Chinese and English databases, will be searched: China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM), WanFang Database, the Cochrane Library, PubMed, EMbase, will be searched from inception to December 2020 for potentially eligible RCTs. Only human researches will be included. Search terms are moxibustion, childhood asthma, pediatric asthma. And the equivalent search terms will be using for Chinese databases. This search strategy will be modified for the other databases.

Participant or population: All previous studies including children (aged 0-18) diagnosed with asthma will be considered for inclusion. All eligible children with asthma will be enrolled without regard to sex, race and education background.

Intervention: The intervention method used in the experimental group must be moxibustion. All forms of moxibustion will be considered, including but not limited to suspended moxibustion, direct moxibustion, scarring moxibustion and herb-partition moxibustion. The combination therapies of moxibustion with other therapies will also be considered.

Comparator: Trials involving the following forms of control will be considered: (1) conventional pharmacological (antipsychotic drugs); (2) nonpharmacological treatments; (3) placebo; (4) blank control (no treatment).

Study designs to be included: In this study, only randomized controlled trials (RCTs) which reported in English or Chinese will be considered. And the criteria of interventions, controls and outcomes of interest should be taken into account as follows below. We will exclude the articles of non-RCTs, animal studies, clinical reports, editor comments, narrative reviews, correspondence, annual meeting abstracts and other trials that do not meet the inclusion criteria.

Eligibility criteria: Any diagnostic criteria for SCOPD.

Information sources: In order to obtain importance information which is not available through the previously retrieved, we will also consult the relevant conference papers and reference of published reviews.

Main outcome(s): The primary outcomes of this study are been considered to be the mean change of the scores of the pulmonary function, such as the percentage of the estimated volume of forced expiratory volume in one second (FEV1), and FEV1/forced vital capacity (FVC). The mean scores of the studies endpoint of these scales will be analyzed when no change data available.

Additional outcome(s): The secondary outcomes will include the following: (1). The frequency of asthma attacks; (2). Airway inflammation indicators, such as fractional exhaled nitric oxide (FeNO) and the eosinophil fraction (EOS); (3). Scores of clinical assessment tools for asthma, such as asthma control test (ACT), childhood

asthma control test (C-ACT), and test for respiratory and asthma control in kids (TRACK). (4). Adverse events.

Data management: Outcomes will be compared between the intervention and control groups. The RevMan 5.3 will be used for data analysis.

Quality assessment / Risk of bias analysis: Cochrane Handbook V.5.1.0, the risk-of-bias tool will be utilized to evaluate the risk of bias of the included RCTs. Two trained reviewers (HS and YZ) will conduct the assessment independently, and discussions will be held to resolve any differences. If necessary, a third reviewer (YJ) will be invited. The risk level of each item for the studies will be ranked into 3 levers (low risk, high risk, and unclear risk of bias).

Strategy of data synthesis: The values measured at the endpoint of the treatment period will be used for data analysis. And the individual measurements for each outcome in each participant will be analyzed. The measurements for each participant will be calculated only once.

Subgroup analysis: If the number of the included RCTs is sufficient (≥10), subgroup analysis will be considered to conduct according to the interventions (time and frequency of moxibustion, the forms of moxibustion), participant characteristic (ages, gender), controls, or outcome measures.

Sensibility analysis: The quality and robustness of the articles will be identified by sensitivity analysis on the basis of the blind methods or randomization methods. We will carry out meta-analysis repeatedly after the trials be excluded.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: moxibustion, asthma, child, systematic review, meta-analysis, protocol.

Contributions of each author:
Author 1 - Haiju Sun.
Author 2 - Xiaoyu Li.
Author 3 - Yajun Zhang.
Author 4 - Jiali Lou.
Author 5 - Yongliang Jiang.
Author 6 - Jianqiao Fang.