

**The efficacy and potential mechanism in Animal Model of Allergic Rhinitis Treatment with Acupuncture: A protocol for systematic review and meta analysis**

INPLASY202380110

doi: 10.37766/inplasy2023.8.0110

Received: 26 August 2023

Published: 26 August 2023

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Xu, LL<sup>8</sup>.**ADMINISTRATIVE INFORMATION****Support** - Jiangxi Province's Double Thousand Plan.**Review Stage at time of this submission** - The review has not yet started.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202380110**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 August 2023 and was last updated on 26 August 2023.**INTRODUCTION**

**Review question / Objective** To assess the effect of acupuncture in the improvement of symptoms in Allergic rhinitis by rats model, and to further summarize the underlying mechanisms of acupuncture in the treatment of Allergic rhinitis.

**Condition being studied** Allergic rhinitis (AR) is a symptomatic disorder of the nose resulting from an Immunoglobulin E (IgE) mediated immunological reaction following exposure to allergen [1].

Epidemiological data showed that the incidence of AR in the general population is currently between 10% and 40% with an increasing annual incidence. AR is a common condition and seriously influence patients' physical and mental health and life quality and poses a significant economic burden on individuals and society. As it was

estimated that the annual diabetes-related health expenditure for the treatment of AR in the United States is \$2-5 billion. AR is called "one airway, one disease" together with asthma. According to epidemiology, 40% of AR patients had asthma and up to 80% of patients with asthma are affected by AR. And early diagnosis and appropriate treatment of AR may prevent further development of other diseases. It follows that AR is a global health problem.

At present, the clinical therapeutic regimen for AR mainly includes environmental control, drug therapy, immunotherapy, surgery. Because of insufficient evidence of surgical treatment and receiving difficult in patient, pharmacotherapy is the mainstream treatment of AR. However, drug therapy can have numerous issues and side effects. For example, the intranasal corticosteroid can cause epistaxis, nasal irritation (including dryness, burning and stinging) and headache,

nasal septal perforation. The common side effects of oral antihistamines are constipation, dry mouth, dry eyes, tachycardia and urinary retention. In addition, Allergen-specific immunotherapy is a globally used superior treatment for AR and remains the only treatment available that targets the immunological cause of the disease, but it has potential issues around safety, compliance, and cost. Therefore, the new safe and effective therapeutic approaches are in urgent need.

Acupuncture, a form of traditional Chinese medicine, is the stimulation on acupoints by inserting filiform needles, or by moxibustion for therapeutic purposes. Numerous clinical studies and experimental studies have indicated that there is good curative effect for acupuncture in the treatment of AR with no or minimal side reactions. However, the mechanism of acupuncture treatment in AR is not very clear, which is an area of intense investigation. Accordingly, this study aimed to investigate the mechanism of acupuncture in treating AR through a cross-sectional study, so as to provide a theoretical basis for the treatment of AR.

## METHODS

**Participant or population** Animal model of allergic rhinitis.

**Intervention** All types of acupuncture related interventions, which covers use of needling, acupuncture points or moxibustion.

**Comparator** Black, model or sham acupuncture (SA) group.

**Study designs to be included** All controlled experiments of the effect of acupuncture in a animal model of allergic rhinitis were included.

**Eligibility criteria** Subject type: Animal model of allergic rhinitis, which is sensitized by ovalbumin (OVA). Type of intervention: All types of acupuncture related interventions, which covers use of needling, acupuncture points or moxibustion. Type of control: Allergic rhinitis model group, Sham acupuncture (SA) group or Black group. Types of outcome measures. (1) Indications of animal behavior: Behavioural scoring. (2) Macrodissection: the spleen weights. (3) Micro-pathohistology: the histopathological changes in the nasal mucosa and the number of EOS would be observed by Morphological Method. (4) Changes in immune indexes: ① Diff-Quick staining method: Observing the total number and classification of cells in nasal lavage fluid under a microscope. ② ELISA: The amounts of IL-4, IL-5, IL-13, IFN- $\gamma$ ,

TSLP and sIgE in peripheral blood and nasal lavage fluid; ③ The TSLP level in nasal mucosa was detected by immunohistochemistry.

**Information sources** We searched the following databases: PubMed, Embase, Cochrane Library, China National Knowledge Infrastructure (CNKI), Chinese VIP Information (VIP), Wanfang databases, Chinese BioMedical Literature Database (CBM) from inception to August 2023. The search strategy includes MESH Terms and keywords and search strategy terms for each database are as follows. ("Acupuncture"[Mesh] or "Acupuncture Therapy"[Mesh] or "Acupuncture, Ear"[Mesh] or "Acupuncture Points"[Mesh] or "Moxibustion"[Mesh]) AND ("Rhinitis, Allergic"[Mesh] or Allergic Rhinitides or Rhinitides, Allergic or Allergic Rhinitis) AND ("Mice"[Mesh] OR "Rats"[Mesh] OR "Rabbits"[Mesh] OR mechanism[Title/Abstract] OR animal study[Title/Abstract] OR preclinical study[Title/Abstract]). Reference lists of eligible studies would be hand-searched for eligible trials.

**Main outcome(s)** (1) Indications of animal behavior: Rats behavioural scoring. (2) Macrodissection: the spleen weights. (3) Micro-pathohistology: the histopathological changes in the nasal mucosa and the number of EOS would be observed by Morphological Method. (4) Changes in immune indexes: ① Diff-Quick staining method: Observing the total number and classification of cells in nasal lavage fluid under a microscope. ② ELISA: The amounts of IL-4, IL-5, IL-13, IFN- $\gamma$ , TSLP and sIgE in peripheral blood and nasal lavage fluid; ③ The TSLP level in nasal mucosa was detected by immunohistochemistry.

**Quality assessment / Risk of bias analysis** The risk of bias was assessed independently by 2 reviewers (LYX and ZXH) with the Systematic Review Centre for Laboratory animal Experimentation (SYRCLE) risk of bias tool [16]. Disagreements would be resolved through consultation with a third investigator (XJ) to reach a consensus.

**Strategy of data synthesis** Meta-analysis would be considered only if at least three studies reported sufficient data with the same outcome, of these, the weighted mean difference (WMD) or standardized mean difference (SMD) with 95% CI will be calculated for continuous outcomes. Meta-analyses were carried out by Review Manager (RevMan 5.4). The statistical heterogeneity among the included studies would be evaluated by  $\chi^2$  test and I<sup>2</sup> statistics. The fixed-effect model would be

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used if the heterogeneity was not significant ( $P \geq 0.1$ ,  $I^2 \leq 50\%$ ), while the random-effect model would be used if the heterogeneity was significant ( $P \leq 0.1$ ,  $I^2 \geq 50\%$ ).

**Subgroup analysis** If heterogeneity exists, the sensitivity analysis or subgroup analysis would be performed to explore the cause of heterogeneity. We will carry out subgroup analyses based on the following factors: the different acupuncture treatments, risk of bias assessment.

In addition, if at least 10 studies were included in the meta-analysis, the funnel plot will be constructed and a meta-regression will be performed to look at issues around publication bias.

**Sensitivity analysis** Sensitivity analysis will be achieved by removing one study at a time from the analysis to estimate the stability of the results.

**Country(ies) involved** China.

**Keywords** Allergic Rhinitis, Animal Model, Acupuncture, systematic review, meta analysis.

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