

Is acupuncture combined with fluticasone propionate nasal spray better for persistent allergic rhinitis?

Submission date

17/07/2020

Registration date

22/07/2020

Last Edited

16/10/2023

Recruitment status

No longer recruiting

Overall study status

Completed

Condition category

Ear, Nose and Throat



Prospectively registered



Protocol added



SAP not yet added



Results not yet added and study completed for 1-2 years



Raw data not yet added



Study completed

Plain English Summary

Background and study aims

Allergic rhinitis (AR) is a condition where the inside of the nose becomes inflamed by allergens. The worldwide incidence of AR is 10–25% and studies have shown that the prevalence of AR has increased in recent years. Classic symptoms of AR include rhinorrhea (running nose), nasal obstruction, nasal itching, and sneezing. Moreover, AR also serves as a trigger for other diseases, such as sinusitis (swelling of the sinuses) and asthma. Intranasal glucocorticoids, oral and nasal antihistamines and leukotriene-receptor antagonists are recommended to treat AR. Allergic rhinitis has traditionally been classified as intermittent AR or persistent AR. Intranasal corticosteroids are recommended by international guidelines as first-line drugs for patients with persistent allergic rhinitis, but there are several studies showing that the standard dose fails to effectively control symptoms of persistent AR. This study aims to evaluate the effects of acupuncture combined with fluticasone propionate nasal spray on persistent allergic rhinitis.

Who can participate?

18-65-year-old patients with at least a 2-year history of moderate to severe persistent allergic rhinitis

What does the study involve?

Participants will be randomly allocated to one of two groups. They will not know which group they are allocated to. The treatment group will receive the nasal fluticasone propionate combined with acupuncture and the control group will receive nasal fluticasone propionate. Severity of allergic rhinitis symptoms is measured at the start of the study, weekly after treatment, week 6 and follow-up months 1, 3 and 6.

What are the possible benefits and risks of participating?

Both groups will get treatment and appropriate care. The symptoms of the participants may improve. There are some potential side effects of acupuncture, including bleeding, hematoma, and pain, but these are generally mild and the treatment will be stopped quickly.

Where is the study run from?

China Academy of Chinese Medical Sciences (China)

When is the study starting and how long is it expected to run for?

May 2020 to December 2022

Who is funding the study?

China Academy of Chinese Medical Sciences (China)

Who is the main contact?

Mrs Hong Zhao

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Protocol/serial number

Nil known

Study information

Scientific Title

Effect of acupuncture combined with fluticasone propionate nasal spray in the treatment of persistent allergic rhinitis: a normalized controlled trial

Study hypothesis

Acupuncture combined with fluticasone propionate nasal spray has better efficacy than fluticasone propionate nasal spray in reducing the nasal symptoms of persistent allergic rhinitis, and has a certain after effect.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 07/05/2020, Institute of Acupuncture and Moxibustion Hospital, China Academy of Chinese Medical Science (No.16, Nanxiaojie, Dongzhimennei, Beijing; +86 (0)10 64060868; zhenjislunli@163.com), ref: 2020-05-07

Study design

Multicenter two-armed single-blind randomized controlled interventional trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Condition

Moderate to severe persistent allergic rhinitis

Interventions

Current interventions as of 17/11/2020:

Eligible patients will be randomly assigned into treatment group or control group. The method of randomisation is central competitive randomization. The researchers in different centres will send messages by phone or text message to the Central Randomization System to get random number and allocation groups.

The treatment group will receive the nasal fluticasone propionate combined with acupuncture and the selected acupoints are as follows: DaZhui warming needle (DU14), YinTang (EX-HN3), SiBai (ST 2), YingXiang (LI 20), ShangYingXiang (EX-HN8), ChiZe (LU 5) bilateral, Hegu (LI 4) bilateral. The participants will receive 16 times of acupuncture treatment in 6 weeks. Three times a week in the first 4 weeks; twice a week in the 5th to 6th weeks.

The control group will receive fluticasone propionate nasal spray 100µg per daily for 6 weeks.

The treatment time was 6 weeks. After the treatment, the patients were followed up for 24 weeks, a total of 30 weeks.

Previous interventions:

Eligible patients will be randomly assigned into treatment group or control group. The method of randomisation is central competitive randomization. The researchers in different centres will send messages by phone or text message to the Central Randomization System to get random number and allocation groups.

The treatment group will receive the nasal fluticasone propionate combined with acupuncture and the selected acupoints are as follows: DaZhui (DU14), YinTang (EX-HN3), SiBai (ST 2), YingXiang (LI 20), ShangYingXiang (EX-HN8), ChiZe (LU 5) bilateral, Hegu (LI 4) bilateral. The participants will receive 16 times of acupuncture treatment in 6 weeks. Three times a week in the first 4 weeks; twice a week in the 5th to 6th weeks.

The control group will receive fluticasone propionate nasal spray 110 µg per daily for 6 weeks.

The treatment time was 6 weeks. After the treatment, the patients were followed up for 24 weeks, a total of 30 weeks.

Intervention Type

Other

Primary outcome measure

Severity of allergic rhinitis symptoms measured using Reflective Total Nasal Symptom Score (rTNSS) at baseline and the end of treatment (6 weeks)

Secondary outcome measures

1. Severity of allergic rhinitis symptoms measured using the Reflective Total Nasal Symptom Score (rTNSS) at baseline, weekly after treatment, week 6 and follow-up months 1, 3, 6
2. Severity of non-nasal symptoms measured using Total Non-Nasal Symptom Score (TNNSS) at baseline, weekly after treatment, week 6 and follow-up months 1, 3, 6
3. Severity of ocular symptoms measured using the reflective total ocular symptom score (rTOSS) at baseline, weekly after treatment, week 6 and follow-up months 1, 3, 6
4. Health-related quality of life measured using RQLQ(S) at baseline, week 6 and follow-up months 1, 3, 6
5. Rescue medication use measured using a 3-point scale: 1- nasal/oral antihistamines, 2- nasal glucocorticoids, 3- oral glucocorticoids at baseline, week 6 and follow-up months 1, 3, 6
6. Rhinitis control assessed using the Rhinitis Control Assessment Test (RCAT) at baseline, weeks 4 and 6, and follow-up months 1, 3, 6

Overall study start date

06/05/2020

Overall study end date

31/12/2022

Eligibility

Participant inclusion criteria

1. Age 18 to 65 years old
2. Diagnosed with persistent allergic rhinitis according to the diagnosis of Allergic Rhinitis and its Impaction Asthma, ARIA (WHO, 2008)
3. Meet the criteria for moderate to severe allergic rhinitis: the symptoms have a significant impact on the quality of life. The overall score of ≥ 6 on the Reflective Total Nasal Symptom Score (rTNSS)
4. Presence of nasal symptoms for 2 successive years
5. Agrees to participate in the study willingly and voluntarily and signs the informed consent form

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

A total of 260 participants will be divided into two groups with a 1:1 allocation ratio.

Total final enrolment

260

Participant exclusion criteria

1. Presence of rhinosinusitis, respiratory diseases, acute paranasal sinusitis, or other systemic diseases that may affect allergic rhinitis
2. Patients are allergic to the fumes from moxibustion
3. Has taken nasal/oral decongestants, nasal/oral antihistamines, mast cell membrane stabilizer, glucocorticoid or antileukotrienes within the past 2 weeks; use of drugs the researchers believe are inappropriate
4. Patients who have received specific immunotherapy or systemic hormone therapy within the last year
5. Patients have received the following treatment measures for allergic rhinitis within the past month: acupuncture, moxibustion, inhalation therapy of Chinese medicine and other physical therapy within the scope of traditional medicine, and external treatment of western medicine or other therapies
6. Patient with severe cardiovascular diseases and endocrine diseases

Recruitment start date

01/08/2020

Recruitment end date

01/10/2022

Locations

Countries of recruitment

China

Study participating centre

Acupuncture and Moxibustion Hospital of CACMS

16 Nanxiao St

Dongzhimen

Dongcheng District

Beijing

China

100000

Study participating centre

Beijing Hospital of Traditional Chinese Medicine, Capital Medical University

No. 23, Back Street

Art Museum

Dongcheng District

Beijing

China

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Study participating centre

AnHui Provincial Hospital of Traditional Chinese Medicine

No. 117 Meishan Road

HeFei

China

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Study participating centre

Guangdong Provincial Hospital of Traditional Chinese Medicine

No. 111 Dade Road

Guangzhou

China

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Study participating centre

The First Hospital of Hunan University of Chinese Medicine

No. 95 Shaoshan Middle Road
Changsha
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410000

Study participating centre

HuBei Provincial Hospital of Traditional Chinese Medicine

No.4 Huayuanshan
Wuchang District
Wuhan
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Study participating centre

First Teaching Hospital of Tianjin University of Traditional Chinese Medicine

No. 88 Changling Road
Xiqing District
Tianjin
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Study participating centre

The Second Hospital of HeiLongjiang University of Chinese Medicine

No.411 Guogeli Street
Nangang District
Harbin
China
150009

Study participating centre

Luohu District Hospital of Traditional Chinese Medicine

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Sponsor information

Organisation

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Sponsor type

Research organisation

Website

<http://www.catcm.ac.cn/>

ROR

<https://ror.org/042pgcv68>

Funder(s)**Funder type**

Research organisation

Funder Name

China Academy of Chinese Medical Sciences

Alternative Name(s)

CACMS

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

China

Results and Publications

Publication and dissemination plan

The researchers intend to publish the protocol before February 2021. They plan to publish results in October 2023.

Intention to publish date

01/03/2024

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|---------|--------------|------------|----------------|-----------------|
| Protocol article | | 31/01/2022 | 02/02/2022 | Yes | No |