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

Submission date
17/07/2020

Recruitment status
No longer recruiting

Registration date
22/07/2020

Overall study status
Completed

Last Edited
16/10/2023

Condition category
Ear, Nose and Throat

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 objectives
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; zhenjslunli@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

Health condition(s) or problem(s) studied
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

Completion date
31/12/2022

Eligibility

Key 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

Key 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

Date of first enrolment
01/08/2020

Date of final enrolment
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
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Study participating centre
AnHui Provincial Hospital of Traditional Chinese Medicine
No. 117 Meishan Road
HeFei
China
230031

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
China
410000

Study participating centre
HuBei Provincial Hospital of Traditional Chinese Medicine
No.4 Huayuanshan
Wuchang District
Wuhan
China
430061

Study participating centre
First Teaching Hospital of Tianjin University of Traditional Chinese Medicine
No. 88 Changling Road
Xiqing District
Tianjin
China
300381

Study participating centre
The Second Hospital of HeiLongjiang University of Chinese Medicine
No.411 Guogeli Street
Nangang District
Harbin
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150009

Study participating centre
Luohu District Hospital of Traditional Chinese Medicine
16 Xiantong Road
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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