

Sphenopalatine ganglion stimulation with acupuncture for perennial allergic rhinitis

Submission date 04/03/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/03/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/09/2020	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Allergic rhinitis is inflammation of the inside of the nose caused by an allergen, such as pollen, dust, mould or certain animal danders. It represents a global health problem, affecting 10% to 20% of the population. Chinese doctors have used acupuncture to stimulate the sphenopalatine ganglion to treat more than 130,000 patients in China and have shown it to be more effective than traditional Chinese acupuncture techniques (verum acupuncture [VA]) for moderate to severe perennial allergic rhinitis (PER). The aim of this study is to find out more about why sphenopalatine ganglion stimulation is better than VA in patients with moderate to severe PER.

Who can participate?

Patients aged 18 to 60 years with moderate to severe or severe PER from four hospitals in Beijing, China.

What does the study involve?

Participants are randomly allocated to one of two groups: either sphenopalatine ganglion stimulation with acupuncture or verum acupuncture. A number of tests will be carried out before the beginning of treatment, before and after each session, after the 4-week treatment and in the 4-week follow-up period.

What are the possible benefits and risks of participating?

Participants' symptoms may reduce or disappear. The risks include discomfort, fainting and hematoma (a collection of blood outside of a blood vessel).

Where is the study run from?

Xiyuan Hospital Chinese Academy of Chinese Medical Sciences, Beijing Tongren Hospital Capital Medical University, Beijing Baiwan Chinese Medical Clinic, Beijing Dacheng Acupuncture Hospital.

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

The study will run from January 2014 to October 2015.

Who is funding the study?

Chinese fundamental research funds for the central public welfare research institutes.

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ZZ070852

Study information

Scientific Title

Sphenopalatine ganglion stimulation with acupuncture for perennial allergic rhinitis
a multicentre randomized traditional Chinese acupuncture techniques (verum acupuncture)
controlled trial

Study objectives

The primary objective of the present study is to investigate the advantages of sphenopalatine ganglion stimulation with acupuncture in patients with moderate-severe perennial allergic rhinitis (PER), compared to traditional Chinese acupuncture techniques.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Xiyuan Hospital Ethics Committee, 31/12/2013

Study design

Multicentre randomised assessor-blinded verum acupuncture controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Moderate-severe perennial allergic rhinitis

Interventions

Participants are randomly allocated to one of two groups:

1. Sphenopalatine ganglion stimulation with acupuncture
2. Verum acupuncture

The study includes the following periods in each groups: a run-in period within 1 week before randomization, 4 weeks of treatment with either sphenopalatine ganglion stimulation with acupuncture or verum acupuncture, and a follow-up period of 4 weeks.

Sphenopalatine ganglion stimulation group

The technique was developed by Professor Li Xinwu, doctor of otolaryngology, head and neck surgery department. The doctor uses a disposable needle designed for acupuncture, 35 mm in diameter × 60 mm in length, to stimulate the sphenopalatine ganglion. After local disinfection, the needle will be inserted into the narrow space between the zygomatic arch and the coronoid process mandible, and then it will be gradually inserted around 55 mm in length to the pterygopalatine fossa. Once the needle point touches the sphenopalatine ganglion the patient will have the special needle sensation (radiation towards nose), and the needle will be pulled out immediately, once the doctor see the patient raises his/her hand as a signal for having the special needle sensation. The unilateral phenopalatine ganglion is needed to be stimulated in one session. The treatment consists one or two sessions per week administered over 4 weeks; the majority of patients need only one session a week, and the doctor decides whether a patient needs another session or not according to the physical signs and symptoms.

Verum acupuncture group

The acupoints, including the main and adjunct points, were selected based on the Chinese medicine guidelines for allergic rhinitis developed by exporters. The main points are yingxiang (LI 20) yintang (GV29), fengchi (GB20), fengfu (GB16), zusanli (ST36). The adjunct points are shangxing (GV23), hegu (LI4), koucheliao (LI19), feishu (BL13), pishu (BL20), shenshu (BL23), sanyinjiao (SP36). Doctor will apply two main and two adjunct points according to each patient's

syndrome differentiation. Each point will be inserted with 0.25 mm diameter x 40 mm length disposable needles. The needle will be inserted to a depth of 10-30 mm, according to the points selected. The doctors will manually manipulate the acupuncture needles with de-qi sensation and maintain the needles for 25 minutes. The verum acupuncture treatment consists of two sessions per week, administered over 4 weeks.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

The onset time and duration of the effectiveness produced by each intervention in every session.

Measured before and after each session:

1. The physical sign score (the degree of swelling of the inferior nasal concha)
2. The nasal congestion degree (visual analogue score)
3. The duration of the change in total nasal symptom score after each session (once the patient feels the symptoms alleviate, the duration time will be measured and the result will be recorded in a PAR diary)

Secondary outcome measures

1. Changes in nasal symptoms (between the run-in period and 4 weeks treatment)
2. The changes in the number of days with moderate-severe rhinitis (between run-in period and one-month follow-up)
3. The changes in the total IgE level, number of eosinophils in venous blood, and number of eosinophils in nasal mucus (between the run-in period and after treatment)
4. The change in quality of life (between the run-in period and 4 weeks treatment)
5. The clinic waiting time (between the two groups)

Measured during the run-in period and 4 weeks treatment:

1. Total nasal symptom score (i.e., nasal itching, sneezing, rhinorrhea, nasal congestion)
2. Total non-nasal symptom score (i.e., postnasal drip, tear dropping, eye itching, pain in nose or palate, headache)
4. The IgE, eosinophil number
5. Rhinitis Quality of Life Questionnaire (RQLQ) score

Measured in follow-up period:

The number of days with moderate-severe rhinitis

Overall study start date

01/01/2014

Completion date

30/06/2015

Eligibility

Key inclusion criteria

1. Diagnosis of moderate-severe or severe PER, according to the criteria of allergic rhinitis and its impact on asthma (ARIA) initiative
2. Have had PER for greater than 4 days/week, and greater than 4 consecutive weeks, and disease course is more than 1 year
3. Age range is from 18 to 60 years, either sex
4. Completed AR baseline questionnaire and provided written informed consent
5. The physical sign score is greater than or equal to 1 and the symptom score is greater than or equal to 4

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

96 participants, allowing for a 20% withdrawal rate

Total final enrolment

96

Key exclusion criteria

1. Acute sinusitis, active asthma, or diagnosed or suspicious pneumonia
2. Nasal abnormalities or rhinopolypus (polypoid lesion can be included)
3. Had applied antihistamines, anticholinergics, corticosteroids, decongestants or antibiotics within 2 weeks before enrollment
4. Received systemically administered corticosteroids within 6 months before enrolment or special immune therapy within 1 year
5. Received alternative and complementary modality, i.e. acupuncture or herbal medication for treating AR within 2 months
6. Pregnant woman or someone is planning for pregnancy
7. Suffering serious medical conditions such as uncontrolled hypertension, diabetes mellitus requiring insulin injection, past or current malignant tumour, severe dyslipidaemia or liver and kidney dysfunction, anaemia, active pulmonary tuberculosis, other infectious disease or systemic diseases insufficient for acupuncture treatment
8. Heavy smoker

Date of first enrolment

01/01/2014

Date of final enrolment

30/06/2015

Locations

Countries of recruitment

China

Study participating centre

Xiyuan Hospital Chinese Academy of Chinese Medical Sciences

China

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Study participating centre

Beijing Tongren Hospital Capital Medical University

China

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Study participating centre

Beijing Baiwan Chinese Medical Clinic

China

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Study participating centre

Beijing Dacheng Acupuncture Hospital

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Sponsor type

Research organisation

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

Chinese Academy of Chinese Medical Sciences - The Fundamental Research Funds for the Central Public Welfare Research Institutes (ref: ZZ070852) (China)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/04/2015		Yes	No
Results article	results	20/02/2020	01/09/2020	Yes	No