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Sphenopalatine ganglion stimulation with acupuncture for perennial allergic rhinitis

Submission date
04/03/2014

Recruitment status
No longer recruiting

Registration date
27/03/2014

Overall study status
Completed

Last Edited
01/09/2020

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
Dr Zhang Lu
zhanglu7810@sina.com

Contact information

Type(s)
Scientific

Contact name
Dr Lu Zhang

Contact details
No.1 Xiyuan Caochang Haidian District
Beijing
China
100091
-
zhanglu7810@sina.com

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 rhinitisa 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), kouheliao (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 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 eosnophils in venous blood, and number of eosnophils 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, eosnophil 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
-

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
China
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Sponsor information

Organisation
Chinese Academy of Chinese Medical Sciences (China)

Sponsor details
No.16 Dongzhimenneinanxiaojie Dongcheng District
Beijing
China
100700
-
18611142837@163.com

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