ISRCTN90807007 https://doi.org/10.1186/ISRCTN90807007

Acupuncture for Persistent Allergic Rhinitis

Submission date 11/02/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/02/2009	**Overall study status** Completed	
Last Edited 02/08/2013	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
KW0901

Study information

Scientific Title

Acupuncture for Persistent Allergic Rhinitis: a multicentre randomised sham acupuncture controlled trial

Acronym
Acupuncture for PER

Study objectives
The primary objective of the present protocol is to investigate the effectiveness of acupuncture in patients with moderate-severe persistent allergic rhinitis (PER) in Korea and China, compared to sham acupuncture and a no-acupuncture waitlist status.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Kyung-Hee University Medical Center Ethics Committee gave approval on the 11th February 2009
2. Daegeon Oriental Hospital Ethics Committee gave approval on the 23rd January 2009

Study design
Multicentre randomised, subject and assessor blinded, sham acupuncture and waitlist controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Persistent allergic rhinitis

Interventions
The study includes the following periods in all groups: a run-in period of 1 week before randomisation, a treatment (acupuncture or sham) period of 4 weeks (3 sessions/week), and a follow-up period of 4 weeks.

Acupuncture group:
In the acupuncture treatment group, 10 acupuncture points (bilateral LI4, LI20, ST2 and ST36, unilateral EX-1 and GV23) will be inserted with 0.20 mm in diameter x 30 mm in length disposal needles. The needle will be inserted to a depth of 10 - 30 mm, according to the points selected. The participating acupuncture doctors will manually manipulate the acupuncture needles with

de-qi sensation and maintain the needles for 10 minutes with two time manual stimulations, starting and ending point.

Sham acupuncture group:
The insertion sites will be 1 - 1.5 cm from the acupuncture points used for active acupuncture treatment and will be penetrated with the same type of acupuncture needles; the needle will be inserted to a depth of 3 - 5 mm with a perpendicular direction using hollow pool in a shallow needling technique to avoid de-qi. The needle is then rotated one time in order to preserve patient blinding.

Waitlist:
Participants who will be allocated to waitlist will receive no acupuncture or sham acupuncture treatments throughout the 4 weeks. After 4 weeks, if participants elect to try the acupuncture treatment, the active acupuncture treatment will be provided, acupuncture treatment period of 4 weeks (3 sessions/week).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Changes in self-reported nasal symptoms during 7 days after 12 sessions/4 weeks acupuncture treatment and one-month follow-up.

Secondary outcome measures
Measured after 12 sessions/4 weeks acupuncture treatment:
1. Rhinitis Quality of Life Questionnaire (RQLQ) score
2. Total non-nasal symptom score (i.e. headache, itching, pain, eye dropping)

Measured during follow-up period:
3. Quantity of conventional relief medication use

Overall study start date
01/03/2009

Completion date
30/04/2010

Eligibility

Key inclusion criteria
1. Diagnosis of PER, with moderate-severe or severe degree, according to the criteria of Allergic Rhinitis and its Impact on Asthma (ARIA) initiative
2. Completed baseline AR diary and provided written informed consent
3. Aged greater than or equal to 18 years of age, either sex
4. Recruited from each centre by the use of local newspaper advertisements and posted notices at each site
5. Have had PER for greater than 4 days/week, and greater than 4 consecutive weeks

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
233 participants, allowing for a 20% withdrawal rate

Key exclusion criteria
1. 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
2. Congenital nasal abnormalities
3. Sinusitis or active asthma
4. Operation history
5. Received systemically administered corticosteroids within 6 months before enrolment
6. Received alternative and complementary modality, i.e. acupuncture or herbal medication for treating AR within 6 months

Topical oral and nasal H1 blockers, or corticosteroid, or nasal anti-cholinergic medication will be stopped before 1 week before enrolment.

Date of first enrolment
01/03/2009

Date of final enrolment
30/04/2010

Locations

Countries of recruitment
China

Korea, South

Study participating centre
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Sponsor information

Organisation
Korea Institute of Oriental Medicine (South Korea)

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Sponsor type
Research organisation

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ROR
https://ror.org/005rpmt10

Funder(s)

Funder type
Research organisation

Funder Name
Korea Institute of Oriental Medicine (South Korea) - The Acupuncture, Moxibustion and Meridian Research Project (ref: K09050)

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	14/07/2009		Yes	No
Results article	results	01/03/2013		Yes	No