

Acupuncture for treating Persistent Allergic Rhinitis with comorbid Chronic Maxillary Sinusitis

Submission date 06/03/2009	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 16/03/2009	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 01/04/2010	Condition category Ear, Nose and Throat	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

KI0901

Study information

Scientific Title

Acupuncture for treating Persistent Allergic Rhinitis with comorbid Chronic Maxillary Sinusitis: a randomised sham-controlled pilot trial

Acronym

Acupuncture for PER with CMS

Study objectives

This study is aimed to test the feasibility of a randomised sham-controlled clinical trial regarding efficacy and safety of acupuncture treatment for comorbid state of persistent allergic rhinitis (PER) and non-infectious chronic maxillary sinusitis (CMS).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Daegeon Oriental Hospital Ethics Committee, approved on 23/01/2009.

Primary study design

Interventional

Study design

Double-blind randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Allergic rhinosinusitis

Interventions

This is a randomised, subject and assessor blinded, sham acupuncture controlled trial.

Participants will receive active or sham acupuncture treatment 3 times per week for 4 weeks and will be followed up for 4 weeks by specialists in traditional Korean medicine.

Treatment sites for active acupuncture treatment:

Six local (facial) and 4 distant acupoints from face were selected. Facial acupoints are EX-1, GV23, LI20 (bilateral), ST2 (bilateral) and distant acupoints are left-sided acupoints of LU9, SP3, LU10 and HT8.

Treatment sites for sham acupuncture treatment:

Non acupoints matched with and adjacent to acupoints in active acupuncture group

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Daily total nasal symptom score (TNSS) of participants recorded on diaries. TNSS is a summation of four nasal symptom scores graded by 5-point-Likert scale (0 = none, 1 = mild, 2 = moderate, 3 = severe, 4 = very severe). These nasal symptoms are nasal obstruction, rhinorrhea, sneezing and pruritus.

Weekly average of daily TNSS from 1 week before treatment initiation to 8th week of study will be calculated and analysed. Primary endpoint will be between the duration of 1 week before treatment initiation and the last (4th) week of active or sham acupuncture treatment.

Key secondary outcome(s)

1. Change in paranasal X-ray. Timepoints of assessment: baseline, 4 weeks and 8 weeks after baseline
2. Rhinitis Quality of Life Questionnaire (RQLQ) score. Timepoints of assessment: baseline, 4 weeks and 8 weeks after baseline
3. Total non-nasal symptom score (i.e. headache, itching, pain, eye dropping) of which grading method is the same as TNSS. Timepoints of assessment: from -1st week (run-in period) of baseline to the 8th week after baseline. Weekly average of daily total non-nasal symptom score will be observed.

Completion date

30/04/2010

Eligibility

Key inclusion criteria

This trial will be carried out for male or female aged between 18 and 60 with following conditions:

1. Persistent allergic rhinitis with moderate-to-severe or severe symptoms according to the guideline of Allergic Rhinitis and its Impact on Asthma (ARIA) initiative
2. Symptoms of chronic rhinosinusitis by ARIA guideline with the impression of maxillary sinusitis presented on Water's view X-ray

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Serious medical conditions in cardiovascular, pulmonary gastrointestinal, genitourinary, neurologic and endocrine system all of which can affect acupuncture treatment

2. Acute/chronic respiratory infections that need systemic antibiotics or anti-tuberculosis agents within 14 days before enrolment
3. Anatomic malformation or history of nose surgery
4. Smoking over 9 cigarettes per day
5. Systemic corticosteroid administration within 6 months before enrolment
6. Any experience of acupuncture or herbal medicine for nasal symptoms within 6 months before enrolment

Date of first enrolment

09/03/2009

Date of final enrolment

30/04/2010

Locations

Countries of recruitment

Korea, South

Study participating centre

Korea Institute of Oriental Medicine

Daejeon

Korea, South

305-811

Sponsor information

Organisation

Korea Institute of Oriental Medicine (South Korea)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration