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Acupuncture for treating Persistent Allergic Rhinitis with comorbid Chronic Maxillary Sinusitis

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

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
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.

Study design
Double-blind randomised 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
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 measure
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.

Secondary outcome measures
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.

Overall study start date
09/03/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

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
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Sponsor information

Organisation
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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