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Study protocol for a pragmatic randomised controlled trial in general practice investigating the effectiveness of acupuncture against migraine

Submission date
01/02/2008

Recruitment status
No longer recruiting

Registration date
28/02/2008

Overall study status
Completed

Last Edited
23/04/2008

Condition category
Nervous System Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI070694

Study information

Scientific Title
Study protocol for a pragmatic randomised controlled trial in general practice investigating the effectiveness of acupuncture against migraine and to examine changes in brain perfusion using SPECT tomography to examine the consequences of the different interventions

Study objectives
Individualised acupuncture is able to reduce the intensity and frequency of pain in migraine to a greater extent than the conventional treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee for Clinical Trials of Andalucia (Comité Autonómico de Ensayos Clínicos de Andalucía). Date of approval: 30 January 2007 (ref: acta 11/06)
2. Local Ethics Committee for Clinical Trials, University Hospital of Valme of Seville (Comité Local de Ensayos Clínicos Hospital Universitario de Valme de Sevilla), Date of approval 4 December 2006 (ref: acta 30 november 2006)
3. Research Ethics Committee of the University Hospital, Virgen de las Nieves de Granada (Comisión de Investigación del Hospital Universitario Virgen de las Nieves de Granada) Date of approval: 21 March 2006

Study design
Randomised controlled multi-centre pragmatic study, with three arms.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Migraine

Interventions

A. Verum acupuncture, 30 min per session, 8 sessions over 8 weeks: Individualized treatment on the basis of diagnosis in accordance with Traditional Chinese Medicine (TCM), which the acupuncture physician may modify in accordance with the evolution of the patient's symptoms
B. Sham acupuncture, 30 min per session, 8 sessions over 8 weeks: The patients who are randomly assigned to this group will be given minimal acupuncture (the real insertion of acupuncture needles, to a depth of less than 3 mm) at 5 bilateral non-acupuncture points located 1.5 cm from the mean dorsal line and lumbar curve
C. Conventional treatment for 8 weeks: The patients will be given the conventional treatment prescribed by their GP

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The difference in the number of Days With Migraine (DWM) between the baseline period and the period spanning weeks 9-12 (DWM1).

Secondary outcome measures
1. DWM between the baseline period and the period spanning weeks 21-24 (DWM2) after randomization.
2. Change in the health-related quality of life between the baseline, final and follow-up periods, assessed by the 12-item Short Form health survey
3. Days free from pain
4. Proportion of patients with at least 50% fewer headaches during the period spanning weeks 9-12, in comparison with the baseline situation
5. Days off work, or of incapacity to perform daily activities
6. Change in the consumption of symptomatic/analgesic and prophylactic medication for migraine attacks, according to the patient's record of the name of the drug and the daily dose consumed, between the baseline period, the end of treatment and after 6 months
7. Change recorded on Goldberg's Depression/Anxiety Scale between the baseline period, the end of treatment and after the follow-up period
8. Difference in the results of the Spanish version of the Headache Impact Test, between the baseline period, the end of treatment and after the follow-up period
9. SPECT: The following values will be calculated for the semi-quantitative analysis of the images:
9.1. Percentage change of the mean value of counts per pixel for each region of interest
9.2. We shall also calculate an Index of Laterality (IL)

Overall study start date
01/02/2008

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. At least 18 years old
2. Diagnosed with migraine, in accordance with the principles of the International Headache

Society and the recommendations for clinical trials published by the same Society
3. With or without aura
4. With a frequency of migraine attacks of 2-6 times per month
5. With a minimum chronicity of one year
6. Onset of symptoms at an age of less than 50 years
7. Have completed the headache diary
8. Have signed informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
270

Key exclusion criteria
1. Acupuncture during the previous 12 months
2. Incapacity to distinguish between tensional headache and migraine
3. Secondary headaches
4. Contraindication to acupuncture (pregnancy, generalised dermopathy, treatment with anticoagulants, thrombocytopenia) or to the performance of Single-Photon Emission Computed Tomography (SPECT) techniques (cerebrovascular accident, traumatic brain injury, alcohol or drug abuse, severe psychiatric disorders)
5. Inability to complete the questionnaires or to reply to the assessor's questions

Date of first enrolment
01/02/2008

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Spain

Study participating centre
Centro de Salud
Dos Hermanas
Spain
41700

Sponsor information

Organisation
Carlos III Health Institute (Spain)

Sponsor details
C/ Sinesio Delgado, 6
Madrid
Spain
28029

Sponsor type
Research organisation

Website
http://www.isciii.es/htdocs/en

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Research organisation

Funder Name
Healthcare Research Fund of the Carlos III Health Institute (Project No. PI070694) (Spain)

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	14/04/2008		Yes	No