

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	☐ Prospectively registered
Registration date 28/02/2008	Overall study status Completed	☒ Protocol
Last Edited 23/04/2008	Condition category Nervous System Diseases	☐ 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

Protocol serial number

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 Andalucía (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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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

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