

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

<b>Submission date</b> 01/02/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/02/2008	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 23/04/2008	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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 dermatopathy, 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?
<a href="#">Protocol article</a>	Protocol	14/04/2008		Yes	No