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# Efficacy and safety of Acupuncture for Migraine Prophylaxis - a multicenter, randomized, controlled clinical trial

**Submission date**
24/05/2007

**Recruitment status**
No longer recruiting

**Registration date**
26/06/2007

**Overall study status**
Completed

**Last Edited**
11/07/2019

**Condition category**
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**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**
SF-2005-2

# Study information

### Scientific Title
Efficacy and safety of Acupuncture for Migraine Prophylaxis - a multicenter, randomized, controlled clinical trial

### Acronym
AMP

### Study objectives
Acupuncture could be an option to prevent migraine attacks in comparison to standard medicine therapy (flunarizine).

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved by the Research Ethical Committee of the Beijing Hospital of Traditional Chinese Medicine on 24/05/2007 (ref: 200704)

### Study design
Multicentre randomised single blind controlled study

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Migraine

### Interventions
The 140 migraine sufferers are randomly allocated to two different groups:
1. Treatment group: At least three acupuncture sessions per week and placebo medicine once a day for 4 weeks.
2. Control group: At least three sham-acupuncture sessions per week and medicine (flunarizine) once a day for 4 weeks.

The patients are asked to receive acupuncture 3 times a week. However, those who require will receive extra acupuncture sessions.

Each acupuncture session lasts for 30 min. The dose of flunarizine / placebo is 10 mg per day for 2 weeks and 5 mg per day in the next 2 weeks.

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
flunarizine

### Primary outcome measure
The efficacy of acupuncture for migraine prophylaxis was assessed by the following:
1. Visual Analogue Scale (VAS) to assess the severity of migraine pain
2. Short-From of McGill Pain Questionnaire (SF-MPQ)
3. Change in frequency and duration of migraine attacks

The outcome measures above will be assessed before the treatment, at 1 week, 2 and 4 weeks during the treatment, and then every month for 3 months. If necessary, the assessments will be repeated 6 months after the treatment.

### Secondary outcome measures
1. Intake of acute-medication
2. Severity of adverse effects
3. Change in the frequency of nausea, vomiting and other correlative symptoms

The outcome measures above will be assessed before the treatment, at 1 week, 2 and 4 weeks during the treatment, and then every month for 3 months. If necessary, the assessments will be repeated 6 months after the treatment.

### Overall study start date
01/06/2007

### Completion date
30/06/2009

## Eligibility

### Key inclusion criteria
1. Patients suffering from migraine without frequent aura (more than 2 migraine attacks in 4 weeks), diagnosed according to criteria of the International Headache Society
2. Male or female
3. Aged 18-65 years
4. Patients who had not used acupuncture or drugs with migraine prophylactic effects within the last 3 months

### Participant type(s)
Patient

**Age group**
Adult

**Lower age limit**
18 Years

**Upper age limit**
65 Years

**Sex**
Both

**Target number of participants**
140

**Total final enrolment**
140

**Key exclusion criteria**
1.Tension-type headache, Cluster headache and other primary headaches
2. Secondary headache and other neurological diseases
3. Neuralgia of the face or head
4. Pregnancy, nursing mother or insufficient contraception
5. Use of prophylactic migraine medication in the last 3 months
6. Therapy with beta-blocker in the last 3 months
7. Intake of antipsychotic or antidepressant drugs
8. Participation in another clinical trial
9. Have family history of depression, Parkinsons disease and other extrapyramidal diseases

**Date of first enrolment**
01/06/2007

**Date of final enrolment**
30/06/2009

# Locations

**Countries of recruitment**
China

**Study participating centre**
**No.23 Meishuguanhou Street**
Beijing
China
100010

# Sponsor information

### Organisation
The Beijing Administration of Traditional Chinese Medicine (China)

### Sponsor details
No.5 Xiaoqudeng lane
Meishuguanhoujie
Dongcheng Districk
Beijing
China
100010

### Sponsor type
Government

### Website
http://www.bjtcm.gov.cn/index.jsp

### ROR
https://ror.org/05damtm70

## Funder(s)

### Funder type
Government

### Funder Name
The Beijing Administration of Traditional Chinese Medicine, Capital Medical Development Research Fund (China)

## 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 | 24/04/2009 | | Yes | No |
| Results article | results | 01/08/2011 | 11/07/2019 | Yes | No |