

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

Submission date 24/05/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/06/2007	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 11/07/2019	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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-Form 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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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)

ROR

<https://ror.org/05damtm70>

Funder(s)

Funder type

Government

Funder Name

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?
Results article	results	01/08/2011	11/07/2019	Yes	No
Protocol article	protocol	24/04/2009		Yes	No