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

Submission date	Recruitment status	[_] Prospectively registered
24/05/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/06/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/07/2019	Nervous System Diseases	

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)

Primary study design
Interventional

Study design
Multicentre randomised single blind controlled study

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-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.

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

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

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