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A clinical trial of acupuncture as prophylaxis for Menstrually Related Migraine (MRM)

Submission date
29/11/2012

Recruitment status
No longer recruiting

Registration date
19/12/2012

Overall study status
Completed

Last Edited
13/09/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Migraine is a condition that causes attacks of headaches, and often other symptoms such as feeling sick or being sick. When migraine attacks occur during periods this is called menstrually related migraine (MRM). About 6 in 10 women who have migraine have this type of pattern. This aim of this study is to test the effectiveness of acupuncture for the treatment of MRM. Acupuncture is a treatment derived from ancient Chinese medicine in which fine needles are inserted at certain sites in the body.

Who can participate?
Women with menstrually related migraine.

What does the study involve?
Patients will be randomly divided into two different groups. One group will be treated with acupuncture and a placebo (dummy) medicine while the other group will be treated with sham acupuncture and naproxen tablets. All treatments are administered for 3 months. Patients will record their headaches in a diary for the 3 months during treatment and one month after treatment. Assessments will be conducted at the start of the study and at follow-up weeks 12 and 16.

What are the possible benefits and risks of participating?
The treatment may reduce the frequency and intensity of headaches. Possible risks include discomfort or bruising at the sites of needle insertion, feeling sick, or feeling faint after each treatment.

Where is the study run from?
Beijing Traditional Chinese Medical Hospital affiliated with Capital Medical University, the Third Hospital of Peking University, Beijing Tiantan Hospital affiliated with Capital Medical University, and Xiyuan Hospital affiliated with China Academy of the Chinese Medical Sciences (CACMS).

When is the study starting and how long is it expected to run for?
This study started in December 2011 and is expected to run for two years.

Who is funding the study?
1. Beijing Municipal Science and Technology
2. Commission (China) Beijing Hospital of Traditional Chinese Medicine (China)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
JJ2011-03

Study information

Scientific Title
To assess the therapeutic effects on acupuncture as prophylaxis for menstrually related migraine: a multicentre randomised controlled trial

Acronym
MRM

Study objectives
Pre-clinical trials have shown that acupuncture is effective in treating migraine, especially for the prevention of migraine. This study is to verify the efficacy of acupuncture as prophylaxis for MRM.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Beijing Hospital of Traditional Chinese Medicine Research Ethical Committee, 10/05/2012, ref: 201212

Study design
Multicenter single-blind randomized controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Menstrually related migraine (MRM); Acupuncture; Prophylaxis treatment

Interventions
A total of 184 patients are randomly divided into two different groups:

1. Treatment group: Acupuncture (preventive treatment on migraine and premenstrual conditioning) and placebo medicine
2. Control group: Sham acupuncture and medicine (Naproxen Sustained Release Tablets)

Patients in both groups are asked to receive acupuncture twice a week, each session lasts for 30 min. Both Naproxen and placebo are taken 0.5 g once per day, from the third day (±1 day accepted) before menstruation comes to the end of menstruation period.

All treatments are administered for 3 months (consecutive menstrual cycles).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. The change of migraine days inside the menstrual cycle
2. The proportion of responders (defined as the proportion of patients with at least a 50% reduction in the number of menstrual migraine days)

Recording headache diaries for four continuous menstrual cycles that included three months (consecutive menstrual cycles) during treatment and one month (menstrual cycle) after treatment.

All assessments will be conducted at the baseline and at week 12 and 16 follow-up.

Key secondary outcome(s))
1. The change of migraine days outside the menstrual cycle
2. Duration of migraine attack
3. Visual analogue scale (VAS, 0 to 10 cm) for pain
4. Amount of migraine medication used

Recording headache diaries for four continuous menstrual cycles that included three months (consecutive menstrual cycles) during treatment and one month (menstrual cycle) after treatment.

All assessments will be conducted at the baseline and at week 12 and 16 follow-up.

Completion date
30/12/2013

Eligibility

Key inclusion criteria
1. Patients who met diagnostic criteria for menstrually related migraine (International Headache Society Classification of Menstrually Related Migraine, 2nd edn, 2004)
2. Regular menstrual cycle lasting 30±10 days
3. Be able to predict the cycle and the onset period of menstrual related migraine
4. Patients suffered a repeated migraine attacks, frequency of non-menstrual migraine is more than once a month
5. Effective contraception and no plan to become pregnant during the study
6. Patients who took part in the trial voluntarily and signed the informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
170

Key exclusion criteria
1. Patients who are diagnosed as chronic migraine(headache caused by drug abuse is included), tension-type headache, cluster headache, algopsychalia tension-type headache, cluster headache, other primary headache disorders
2. Patients suffered relatively severe systemic disease, such as cardiovascular diseases, acute infectious disease, hematopathy, endocrinopathy, allergy and methysis
3. Patients suffered otorhinolaryngology diseases which may cause headache, such as glaucoma, otitis, sinusitis, pericoronitis of wisdom tooth
4. Patients who suffered headache caused by intracranial pathological changes, such as intracranial infection, brain tumours, subarachnoid hemorrhage
5. The blood pressure is not controlled ideally
6. The menses cycle is erratical because of polycystic ovary and other gynecologic diseases, and

the time of which is hard to predict
7. Patients who have been taking contraceptives or accepting other hormone therapy during the last 3 months

Date of first enrolment
30/12/2011

Date of final enrolment
30/12/2013

Locations

Countries of recruitment
China

Study participating centre
Beijing Traditional Chinese Medical Hospital affiliated with Capital Medical University
China
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Study participating centre
Third Hospital of Peking University
China
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Study participating centre
Beijing Tiantan Hospital affiliated with Capital Medical University
China
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Study participating centre
Xiyuan Hospital affiliated with China Academy of the Chinese Medical Sciences
China
-

Sponsor information

Organisation
Beijing Municipal Science and Technology Commission (China)

ROR
https://ror.org/034k14f91

Funder(s)

Funder type
Government

Funder Name
Beijing Municipal Science and Technology Commission (China)

Funder Name
Beijing Hospital of Traditional Chinese Medicine (China)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		26/08/2022	13/09/2022	Yes	No
Protocol article	protocol	06/11/2013		Yes	No