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Acupuncture for the prevention of chronic migraine attacks

Submission date
11/09/2017

Recruitment status
No longer recruiting

Registration date
25/09/2017

Overall study status
Completed

Last Edited
25/06/2024

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Approximately 1.4% to 2.2% of the general population suffers from chronic migraine (CM). This is when a headache lasts for more than 15 days a month. Acupuncture (an ancient Chinese medicine that inserts fine needles in the body) may be a choice to treat chronic migraine, when pharmacological prophylaxis (a treatment of medication) is not suitable. However, the efficacy of acupuncture has not been confirmed The aim of this study is to evaluate the efficacy of acupuncture compared with a medication called topiramate in chronic migraine patients.

Who can participate?
Adults aged 18 to 65 who have diagnosed chronic migraines.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive verum acupuncture and placebo medicine in the treatment group. Those in the second group are treated with sham acupuncture and medicine (topiramate). All participants are given for 3 months of treatment and 2 months of follow-up. Participants are assessed for their amount of days they experience headaches.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in their chronic migraine symptoms. Participants may experience transient pain or soreness, or other possible problems including bleeding, bruising or local paresthesia (tingling) around the spot of the needle. During the topiramate titration and maintenance period, participants may experience paresthesia, difficulty with memory, dyspepsia (indigestion), fatigue, dizziness, somnolence (sleepiness) and nausea.

Where is the study run from?
Beijing Hospital of Traditional Chinese Medicine (China)

When is the study starting and how long is it expected to run for?
July 2017 to December 2022

Who is funding the study?
Beijing Municipal Science & Technology Commission (China)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Z171100001017033

Study information

Scientific Title
Acupuncture as prophylaxis for chronic migraine: A single-blinded, double-dummy, randomised controlled trial

Study objectives
The aim of this study is to evaluate the efficacy of acupuncture compared with topiramate in chronic migraine patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethical Committee of Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University, 21/07/2017, ref: 2017BL-045-01

Study design
This is a single-blind, randomized controlled clinical trial. A total of 60 participants will be randomly assigned to two different groups. Participants will receive verum acupuncture and placebo medicine in the treatment group, while participants in the control group will be treated with sham acupuncture and medicine (topiramate). All participants will be given for 3 months of treatment and 2 months of follow-up.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Chronic migraine (CM)

Interventions
Participants receive verum acupuncture and placebo medicine in the treatment group, while participants in the control group are treated with sham acupuncture and medicine (topiramate). All participants are given 3 months of treatment and 2 months of follow-up.

The central randomization is performed by the Research Center of Clinical Epidemiology affiliated to Peking University in China, which use block randomization to generate the random allocation sequence and prepare predetermined computer made randomization opaque sealed envelopes. The envelopes are numbered consecutively and connected into a strain. Each envelope is separated from the strain and then opened in sequence only after baseline period when the participants are registered in the trial. In our study, the participants are informed that they have a 50% chance of being allocated in either of the two groups: verum acupuncture and placebo medicine group and sham acupuncture and medicine (topiramate).

Treatment group: In the treatment group, verum acupuncture treatment consists of three 30-minute sessions per week, administered over 12 weeks, and placebo medication was taken for 12 consecutive weeks. The acupuncture points, including both obligatory and additional points, are selected based on the consensus of clinical experiences of acupuncture experts. The obligatory points include DU20 (Baihui), DU24 (Shenting), GB13 (Benshen), GB8 (Shuaigu), and GB20 (Fengchi). Additional points can be chosen according to syndrome differentiation of meridians: Shaoyang headache (TE-GB): SJ5 (Waiguan), GB34 (Yanglingquan); Yangming headache (LI-ST): LI4 (Hegu), ST44 (Neiting); Taiyang headache (SI-BL): BL60 (Kunlun), SI3 (Houxi); Jueyin headache (PC-LR): LR3 (Taichong), GB40 (Qiuxu); Needles are inserted in an appropriate angle to a depth of 10-15 mm and manually manipulated by lifting, thrusting, and twirling methods to produce a characteristic sensation known as "De Qi" (feeling of needle sensation refers to tenseness around the needle felt by the practitioner and numbness, distension, soreness, and heaviness around the point felt by the patient). Needles are stimulated manually at least 10 s, then the needles are retained for 30 minutes.

Control group:
The control group is treated with topiramate and three 30-minute sessions of sham acupuncture treatment per week for 12 weeks. Both topiramate and placebos are taken for 12 consecutive weeks. The placebo medicine have exactly the same appearance as true medicines (topiramate). The treatment phase consisted of a 4-week titration period and an 8-week maintenance period. During the titration period, participants are given topiramate 25 mg/day at bedtime for 1 week, followed by weekly increases of 25 mg up to either 100 mg/day of topiramate or to the maximal tolerated dose. Starting in week 2, topiramate are given daily in equally divided twice daily doses. During the maintenance period, a stable topiramate dose of at least 50 mg/ day is required.

The sham points, including 2 points on the arms and 3 points on the legs, are defined as unrelated to headache based on a vast amount of TCM reference books and the consensus of clinical experiences of acupuncture experts. The sham points include LI15 (Jianyu), PC3 (Quze), GB35 (Yangjiao), LR7(Xiguan), and ST37 (Shangjuxu). Needles are inserted 10-15 mm in depth and manually manipulated with rotation methods to produce a characteristic sensation known as "De Qi". Technique of mild reinforcing and attenuating is applied, and the needles are retained for 30 minutes.

All participants are permitted to treat acute headaches as required, Ibuprofen was recommended to all patients as their first choice for acute medication. The name and dosage of these medications are required to be recorded in the headache diaries.

Intervention Type
Other

Primary outcome measure

Monthly number of headache days (any intensity) is measured using the headache diary at baseline period (4 weeks before the beginning of treatment) and 12 weeks.

Secondary outcome measures
1. Number of days with acute headache medications is measured using headache diary at baseline period (4 weeks before the beginning of treatment) and 12 weeks.
2. Migraine Disability is measured using the MIDAS score at baseline, 12 weeks, and 24 weeks.
3. Migraine-Specific Quality-of-Life Questionnaire/Headache impact test measured using the MSQ/HIT6 questionnaire at baseline, 12 weeks, and 24 weeks.
4. Anxiety is measured using the STAI/BDI-II questionnaires at baseline, 12 weeks, and 24 weeks.

Overall study start date
21/07/2017

Completion date
07/12/2022

Eligibility

Key inclusion criteria
1. Diagnosed as chronic migraine according to the diagnostic criteria specified by the International Classification of Headache Disorders(International Classification of Headache Disorders-Third edition (beta version) [ICHD-β])
2. Aged between 18 and 65 years old
3. No prophylaxis treatments with acupuncture or drugs in the past 3 months
4. Written informed consent provided

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Tension-type headache, cluster headache, and other primary headaches
2. Relatively severe systemic diseases(cardiovascular disease, acute infectious disease, hematopathy,endocrinopathy, allergy, and methysis)
3. Headache caused by otorhinolaryngology diseases or intracranial pathological changes

4. Secondary headache and other neurological diseases
5. Pregnancy, lactation, or insufficient contraception

Date of first enrolment
07/05/2018

Date of final enrolment
23/05/2022

Locations

Countries of recruitment
China

Study participating centre
Beijing Hospital of Traditional Chinese Medicine
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/057vq6e26

Funder(s)

Funder type

Government

Funder Name
Beijing Municipal Science & Technology Commission

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal and of the study research data and conclusion by 31/12/2022.

Intention to publish date
31/05/2023

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	31/05/2018	13/05/2019	Yes	No
Results article		11/06/2024	25/06/2024	Yes	No