ISRCTN11800433 https://doi.org/10.1186/ISRCTN11800433

A study on the neurobiological mechanism of acupuncture treatment for migraine

Submission date
06/08/2017

Recruitment status
No longer recruiting

Registration date
08/09/2017

Overall study status
Completed

Last Edited
04/03/2022

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
A migraine is a moderate or severe headache felt as a throbbing pain on one side of the head. Acupuncture is a popular form of complementary medicine for migraine. Recent research showed that verum (true) acupuncture treatment may be associated with long-term reduction in migraine recurrence compared with sham acupuncture. The aim of this study is to compare the effects on brain activity of verum acupuncture and sham acupuncture.

Who can participate?
Patients aged 18 to 65 with migraine

What does the study involve?
Participants are randomly allocated to the verum acupuncture group or the sham acupuncture group. They receive acupuncture for 12 sessions over 4 weeks and 3 months of follow-up. All participants are scanned at the start of the study and at the end of treatment. The number of migraine days is calculated using a headache diary from the start of the study to the 16th week.

What are the possible benefits and risks of participating?
Migraine symptoms may be improved by treatment. The information obtained from this study may benefit future patients with the same condition. In the course of the scan, very few patients who do not feel claustrophobic may feel nausea, chest tightness, palpitation and other symptoms. The risk of drawing blood from the arm includes brief discomfort and/or cyanosis. Despite the small possibility of infection, excessive bleeding, coagulation, or fainting may occur. During acupuncture, participants may experience brief pain or soreness, and other possible problems include bleeding, bluish around the spot of the needle, and fainting.

Where is the study run from?
Beijing Hospital of Traditional Chinese Medicine affiliated to the Capital Medical University (China)

When is the study starting and how long is it expected to run for?
February 2017 to February 2019

Who is funding the study?
National Basic Research Program of China

Who is the main contact?
Dr Lin-Peng Wang
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01/02/2017

Study information

Scientific Title
A study on the neurobiological mechanism of acupuncture treatment for migraine: a randomized controlled trial

Study objectives
Migraine is a disabling and common neurological disorder with high socioeconomic impact , typically characterized by unilateral, throbbing, pulsating headache. According to clinical experience, acupuncture is a popular form of complementary medicine for migraine. Recent researches showed that the verum acupuncture treatment may be associated with long-term reduction in migraine recurrence compared with sham acupuncture. The objective of this study is to to compare the local features of spontaneous brain activity between the verum acupuncture group and the sham acupuncture group and to investigate the possible correlation between clinical variables and brain responses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University, 01/02/2017, ref: 2016BL-081-02

Study design
Single-blind randomized controlled clinical trial

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 to request a patient information sheet

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

Interventions
100 participants will be randomly assigned to the verum acupuncture group and the sham acupuncture group. All participants will receive acupuncture for 12 sessions over 4 weeks and 3 months of follow-up.

Verum acupuncture group
The acupuncture points, including both obligatory and additional points, were 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). Needles will be inserted in an appropriate angle to a depth of 1.5-2.5 cm and manually manipulated by lifting, thrusting, and twirling methods to produce a characteristic sensation known as Deqi (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), and needles will be stimulated manually at least 10 s.

Sham acupuncture group:
The locations of these non-acupoints are described as follows:
Sham-point 1: In the medial arm on the anterior border of the insertion of the deltoid muscle at the junction of deltoid and biceps muscles
Sham-point 2: The edge of the tibia ,1 to 2 cm lateral and horizontal to the Zusanli (ST36)
Sham-point 3: Ulnar side, half way between the epicondylus medialis of the humerus and the ulnar side of the wrist

Sham-point 4: Half between the tip of the elbow and the axilla. These four points are sited distant to the traditionally recognized acupoints or meridians lines. The method will be the same as the verum acupuncture group.

Intervention Type
Other

Primary outcome measure
The number of migraine days during the 4th and 16th week after randomization. The participants are asked to fill in headache diaries from baseline period (4 weeks before the beginning of treatment) to the 16th week after randomization.

Secondary outcome measures
1. Headache impact and quality of life are measured using the Headache Impact Test (HIT-6), the Migraine Disability Assessment questionnaire (MIDAS) and the Migraine-Specific Quality of Life Questionnaire scores MSQ)
2. Anxiety and depression are measured using the Beck Anxiety Inventory (BAI) and Beck Depression Inventory (BDI) scores,and the State-trait Anxiety Inventory (STAI)
3. Sleep quality is measured using the Pittsburgh Sleep Quality Index (PSQI)
4. Cognitive function is measured using the Mini-Mental State Examination (MMSE) and the Montreal Cognitive Assessment (MoCA)
5. Sense of pain is measured using the Quantitative Sensory Testing (QST)

Measured before randomization, 4 and 16 weeks after randomization, and besides the BDI , BAI and QST will be assessed at the first, second and third weeks during treatment.

Overall study start date
01/02/2017

Completion date
01/02/2019

Eligibility

Key inclusion criteria
1. Diagnosed as migraine without aura according to the diagnostic criteria specified by the International Classification of Headache Disorders (International Classification of Headache Disorders-Third edition (beta version) [ICHD-IIIβ])
2. History of migraine at least 1 year before study entry
3. More than 2 migraine attacks within 4 weeks
4. Age between 18 and 65 years old and right-handed
5. No acute migraine treatment with acupuncture or drugs within 24 hours after the beginning of the migraine attack, no prophylaxis treatments with acupuncture or drugs in the past 3 months
6. Written informed consent provided

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Total final enrolment
41

Key exclusion criteria
1. Chronic migraine, tension-type headache, cluster headache, and other primary headaches
2. Secondary headache and other neurological diseases
3. Relatively severe systemic diseases (cardiovascular disease, acute infectious disease, hematopathy,endocrinopathy, allergy, and methysis)
4. Headache caused by otorhinolaryngology diseases or intracranial pathological changes
5. Pregnancy, lactation, or insufficient contraception
6. The use of b-blockers, opioids, antipsychotics, antidepressants, antimaniacals, barbiturates, benzodiazepines, skeletal muscle relaxants, tranquilizers, or tramadols within the last 3 months
7. History of depression, Parkinson’s disease, or other extrapyramidal diseases
8. Magnetic resonance imaging (MRI) contraindications such as claustrophobia and metal objects in patients
9. Not being right-handed as measured by the Edinburgh Handedness Inventory
10. Acupuncture contraindications such as bleeding tendency and local infection
11. Alcohol or drug abusers
12. Participation in another clinical trial

Date of first enrolment
01/02/2017

Date of final enrolment
01/09/2018

Locations

Countries of recruitment
China

Study participating centre
Beijing Hospital of Traditional Chinese Medicine affiliated to the Capital Medical University
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Sponsor information

Organisation
Beijing Hospital of Traditional Chinese Medicine affiliated to the Capital Medical University

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/057vq6e26

Funder(s)

Funder type
Government

Funder Name
National Basic Research Program of China (grant number 2014CB543203)

Results and Publications

Publication and dissemination plan
1. Study protocol published 31/10/2017
2. Study research data and conclusion on pain published 01/02/2020
3. 1-2 papers about acupuncture and neurobiological mechanism published at the end of 2019

Intention to publish date
01/02/2020

Individual participant data (IPD) sharing plan
The 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?
Results article		05/03/2020	04/03/2022	Yes	No