Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of electroacupuncture and manual acupuncture in patients with tension-type headache: a randomized clinical trial

Protocol summary

Study aim

Determining the effectiveness of manual acupuncture and electroacupuncture on intensity and number of days of tension headaches, the amount of painkillers used in acute headaches, anxiety, depression and quality of life.

Design

Clinical trial with control group, with parallel groups, single-blind study, randomized, phase 3 on 75 patients. The online site https://www.sealedenvelope.com was used for randomization.

Settings and conduct

Patients visit the acupuncture clinic of Imam Reza Hospital 3 times a week for 4 weeks. Disposable sterile needles, size 0.25 x 25 mm, are placed in the specified place and depth according to Chinese medicine reference books.. Both groups Patients receive 12 treatment sessions. The follow-up period is 8 weeks

Participants/Inclusion and exclusion criteria

Patients with tension headaches aged 18 to 65 years with the onset of headache under the age of 50, whose treatment started 3 months before the study and continued without any changes during the study. Exclusion criteria: Migraine headache more than one day a month or secondary headaches; severe physical or mental illness; pregnancy; breastfeeding; any type of addiction, acupuncture treatment in the last 6 months and continuous use of headache pain relievers more than 10 days a month for more than 3 months.

Intervention groups

Needles will be inserted in these points for both intervention groups: GB20-GV20-LI4-LV3-EX HN 5-ST8-GB8-SP6-ST36-EX HN 3-SJ 5-LU 7-ST40-REN12-PC6-HT7-BL60. In the electro-acupuncture group, the needles are stimulated with an electro-acupuncture device at points DU 20/EX-HN3-LI4/PC 6-LIV 3/SP 6. Participants in the usual care group (control) continued their previous treatment and completed the questionnaires similarly to the two intervention groups.

Main outcome variables

Pain intensity

General information

Reason for update

1- Sampling has not yet ended, the date has been modified 2- Except for the care provider and investigator who do not have the possibility of blinding in acupuncture studies, the others are blinded 3- In the primary outcome: section of headache hours, the word "average" in this section was incorrect and I delete it.4- The name of the person responsible for general inquiries is modified.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230626058585N1**
Registration date: **2023-10-17, 1402/07/25**
Registration timing: **registered_while_recruiting**

Last update: **2026-02-09, 1404/11/20**
Update count: **2**

Registration date

2023-10-17, 1402/07/25

Registrant information

Name

Seyyed Kazem Farahmand

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-17, 1402/07/25

Expected recruitment end date

2026-03-20, 1404/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of electroacupuncture and manual acupuncture in patients with tension-type headache: a randomized clinical trial

Public title

Investigating the effect of acupuncture on headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients suffering from chronic and episodic tension headache based on the criteria of the International Headache Society (ICHD 3beta) who suffer from headache for more than one year. Age 18 to 65 years Age of onset of headache below 50 years Desire to participate in the study and sign an informed consent Any headache treatment should be started at least 3 months before the study and continued without any changes (except the treatment of acute headache attack) in the last 3 months and during the intervention and follow-up period. These treatments include pain relievers when needed (such as acetaminophen and ibuprofen) and/or preventive medications (such as amitriptyline) or even non-pharmacological treatments (such as relaxation techniques).

Exclusion criteria:

Suffering from migraine headache for more than one day in a month Secondary headaches related to organic disease (for example: cerebral hemorrhage, cerebral thrombosis, vascular malformation, hypertension) Severe physical or mental illness such as seizures, coagulation disorders, heart disease, liver disease, kidney disease and other organs. Pregnancy, breastfeeding or decision to become pregnant during the study period Addiction to smoking, alcohol, drugs Acupuncture treatment in the last 6 months (in order to blind the treatment method, he has never had a history of electro-acupuncture) Continuous use of headache pain relievers more than 10 days a month for more than 3 months (Medication-overuse headache)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked individual using the online site https://www.sealedenvelope.com random allocation into three groups A (electroacupuncture), group B (manual acupuncture) and group C (usual care). Randomization will be done based on Block Randomization with blocks of 6. A block size of 6 will be used for random allocation. The prepared blocks will be placed inside the envelope. According to the order of arrival of patients, one of the envelopes will be randomly selected and based on the obtained blocks, patients will be allocated to groups. Allocation Concealment method: Using sealed and waxed opaque envelopes: In this way, the envelopes will be prepared and printed by one of the team members and random numbers will be placed inside the envelope. The lid of the envelopes will be closed and its contents will not be visible from the outside. Then, first, the purpose of the study is explained to the person who meets the stated conditions, and if the person wishes, he signs the informed consent form and takes an envelope, then opens it and enters one of the three groups based on the contents of the envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

1- in order to know whether electroacupuncture is superior to manual acupuncture or not, blinding will be done in the intervention groups, so that in both groups, the electrodes are connected to the needles, but in the manual acupuncture group, there is no current in wire and only the blinking diode that simulates the electric stimulus can be seen and its sound can be heard. 2- Those who collect and analyze the information and the safety monitoring board do not know the names of the patients and the division of the groups and the assignment of each patient to each group.

Placebo

Not used

Assignment

Parallel

Other design features

However, due to the fact that we do not have any intervention in the control group, we do not have blinding. But in order to know whether electroacupuncture is superior to manual acupuncture or not, blinding will be done in the intervention groups, so that in both groups, the electrodes are connected to the needles, but in the manual acupuncture group, there is no current in wire and only the blinking diode that simulates the electric stimulus can be seen and its sound can be heard.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of mashhad university of medical sciences

Street address
Building number one of Mashhad University of Medical Sciences (Qureshi), in front of University 18, Daneshgah St.

City
Mashhad

Province
Razavi Khorasan

Postal code
39441-91388

Approval date
2023-09-09, 1402/06/18

Ethics committee reference number
IR.MUMS.REC.1402.173

Health conditions studied

1

Description of health condition studied
Tension-type headache

ICD-10 code
G44.2

ICD-10 code description
Tension-type headache

Primary outcomes

1

Description
Average tension headache intensity over 4 weeks

Timepoint
Initially before randomization and 4, 8, 12, weeks after randomization

Method of measurement
Using a visual analog scale (VAS) includes a straight horizontal line marked from 0-10. 0 means no pain and 10 means very severe pain. The participants are asked to Answer the question: How severe was your worst pain in the past 24 hours?, and then mark the point on the line that corresponds to the pain level.

Secondary outcomes

1

Description
The dosage of painkillers for acute headache attacks

Timepoint
Total dose consumed during 4 weeks (time interval: initially before randomization, 4, 8, 12 weeks after randomization)

Method of measurement
The name, number and dose of acute pain reliever are recorded every day, the total dosage is checked every 4 weeks.

2

Description
Assessment of quality of life

Timepoint
At baseline before randomization, 4, 8, 12 weeks after randomization

Method of measurement
Using a 36-item short form survey instrument (SF-36) questionnaire that is used to evaluate people's quality of life, which includes 36 questions for physical and mental health, which are divided into 0-100 scores (0 = worst health condition and 100 = best health condition). .. The average score of 50 is expressed as the normative value for all scales.

3

Description
Assessment of anxiety score

Timepoint
At baseline before randomization, 4, 8, 12 weeks after randomization

Method of measurement
Beck's anxiety questionnaire

4

Description
Assessment of depression status

Timepoint
At baseline before randomization, 4, 8, 12 weeks after randomization

Method of measurement
Beck depression questionnaire

5

Description
Number of headache days

Timepoint
It will be daily recorded by patients. For statistical analysis: Initially, before randomization, and 4, 8, 12 weeks after randomization

Method of measurement
Headaches lasting more than 30 minutes per day are recorded in the headache diary. The response rate is defined as a reduction of more than 50% in the number of headache days.

6

Description
duration of pain attacks

Timepoint
Every day, the hours that the patient had a headache are recorded. for statistical analysis: Initially before randomization and 4, 8, 12, weeks after randomization

Method of measurement
By recording the start and end time of the headache in the diary, the total pain hours in 4 weeks will be

calculated

Intervention groups

1

Description
First intervention group: electroacupuncture: after disinfecting the skin, disposable sterile needles size 25 x 0.25 in points (GB20-GV20-LI4-LV3-EX HN 5-ST8-GB8-SP6-ST36-EX HN 3-SJ 5 -LU 7-ST40-REN12-PC6-HT7-BL60) with a certain depth based on the instructions of Chinese medicine ،are placed on both sides. The needles remain in place for 30 minutes. The needles are connected to the electro device in the distal points of both hands and feet and a local point and are stimulated for 30 minutes. The points that are connected to the electro include: DU 20 /EX-HN3 in head- LI4 / PC 6 in both hands - in both legs LIV 3 / SP 6

Category
Treatment - Devices

2

Description
The second intervention group: manual acupuncture - needles in points (GB20-GV20-LI4-LV3-EX HN 5-ST8-GB8-SP6-ST36-EX HN 3-SJ 5-LU 7-ST40-REN12-PC6-HT7- BL60) with a certain depth according to Chinese medicine instructions, will be placed on both sides and will remain in place for 30 minutes. In order to blind the electrodes, they are connected to the needles, but the passage of the electric current is interrupted and only the flashing diode that simulates the electric stimulus can be seen and its sound can be heard.

Category
Treatment - Devices

3

Description
Control group: The participants in the usual care group continued their previous treatment without any intervention and completed the questionnaires similar to the two intervention groups. After the follow-up period, as a reward, they were treated with acupuncture with or without electro, based on the treatment result. will be placed

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Neurology Clinic of Ghaem Mashhad Hospital

Full name of responsible person
DR Payam Sasannejad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Shirin Shafaee

Position
PHD Student

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Assistant Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available