Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A sham-controlled trial of acupuncture as an adjunct to migraine prophylaxis

Protocol summary

Summary

The objestive of this study is assessing the effect of adding acupuncture to conventional migraine prophylaxis. The inclusion criteria is having more than 3 migraine attacks in a month and inadequacy of three months conventional prophylaxis treatment. The exclusion criteria is absence of a net diagnosis for migraine, and being received acupuncture treatment in the past six months. The study population are patients with migraine who refer to Neurology Clinic of Qaem hospital, Mashhad, Iran. One hundred migraine patients in whom the number of attacks did not drop by 50% after receiving prophylactic medications entered the study. The intervention included True Acupuncture+prophylactic medications in comparison to Sham Acupuncture + prophylactic medications. The Intervention time is one month including 12 sessions of acupuncture treatments every other day. The primary outcome is the number of headache attacks at the baseline, month1, 2,3 and4.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108097265N1**
Registration date: **2013-07-16, 1392/04/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-07-16, 1392/04/25

Registrant information

Name
Hoda Azizi
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2011-03-01, 1389/12/10

Expected recruitment end date

2011-12-31, 1390/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A sham-controlled trial of acupuncture as an adjunct to migraine prophylaxis

Public title

Acupuncture for migraine prophylaxis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: a diagnosis for Migraine; more than 3 migraine attacks in a month; inadequacy of three months conventional prophylaxis treatment; Patient's consent to receive acupuncture Exclusion criteria: Absence of a net diagnosis for migraine; Patient's disapproval; Patients who did not fulfill their treatment sessions; Migraine headaches which are responsive to medications; Patients who had received acupuncture treatment in the past six months.

Age
From **16 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad University of Medical Sciences
Street address
Mashhad University of Medical Sciences-Qorashi building, Daneshgah Street
City
Mashhad
Postal code
Approval date
2011-02-26, 1389/12/07
Ethics committee reference number
89590

Health conditions studied

1

Description of health condition studied
migraine
ICD-10 code
G43.0
ICD-10 code description
Migraine without aura [common migraine]

Primary outcomes

1

Description
the numbers of monthly headache attacks
Timepoint
baseline, and at the end of first month treatment, at the end of the second, third and fourth months from baseline
Method of measurement
patients' self-report of monthly headache frequency

Secondary outcomes

empty

Intervention groups

1

Description
Intervention-True Acupuncture: Inserting needles on true acupoints and maintaining them for 30 minutes in each treatment session, 3 times per week, duration: one month.
Category
Treatment - Other

2

Description
Control- Sham Acupuncture: inserting needles superficially not in real acupuncture points and maintaining them for 30 minutes in each session, 3 times per week, duration: one month.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology clinic, Qaem Hospital
Full name of responsible person
Mohsen Kalhor, Mohsen Foroughipour
Street address
Ahmadabad Street
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi (Vice Chancellor for research)/ Dr. Mahyar Mirheydari
Street address
Qorashi Building, Daneshgah Street
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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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty