

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

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

Protocol summary

Summary

The objective 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

Country

Iran (Islamic Republic of)

Phone

+98 51 1855 2188

Email address

azizih@mums.ac.ir

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

City

Mashhad

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**Contact****Name of organization / entity**

Department of Integrative Medicine, Beijing
University of Chinese Medicine

Full name of responsible person

Amir Reza Golchian

Position

lecturer

Other areas of specialty/work**Street address**

Department of Integrative Medicine, Beijing
University of Chinese Medicine

City

Beijing

Province

Beijing

Postal code**Phone**

00861064286426

Fax**Email**

amirgol67@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Department of Neurology, Faculty of Medicine,
Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Foroughipour

Position

Associate Professor

Other areas of specialty/work**Street address**

Department of Neurology, Faculty of Medicine, Qaem
Hospital

City

Mashhad

Postal code**Phone**

+98 108400001

Fax**Email**

ForoughipourM@mums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Department of Chinese and Complementary
Medicine, School of Traditional and Complementary
Medicine,

Full name of responsible person

Hoda Azizi

Position

Assistant Professor

Other areas of specialty/work**Street address**

School of Traditional and Complementary Medicine,
East Razi Street

City

Mashhad

Postal code**Phone**

+98 51 1852 0282

Fax**Email**

azizih@mums.ac.ir

Web page address**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