

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### The effect of leech therapy on primary headache in patients referring to Cupping unit

#### Protocol summary

##### Summary

This study is a non-randomized clinical trial with parallel control group that conducted in cupping clinic and private office of a neurologist in Shahroud city, Iran. Early-stage sampling will be from July 2009 to late January 2011 that 45 patients enrolled in the study. The target population is patients with primary headache. Sampling is purposive, and assignment to two groups (drug therapy and leech therapy) was non-random. Inclusion criterion: diagnosis of primary headache by neurologist based on diagnostic parameters. Major exclusion criteria: patients with brain tumors and other brain diseases; patients with hemorrhagic disorders. Objective: To determine and compare the intensity and duration of headache in patients with primary headaches before and after leech therapy and drug therapy. Methods: In leech therapy group, the severity and duration of the patient's headache were recorded and then 1-3 leeches were placed behind the patient's ear according to the physician's order. The session of leech therapy lasted about 50-30 minutes. Drug therapy group were patients with symptoms of headache who referred to neurologist and after documentation of the severity and duration of headache were discharged with medication. Patients in this group used one of medication regimens for primary headaches that mainly included a combination of propranolol 40 mg twice a day, nortriptyline 25 mg twice a day, or citalopram 20 mg daily used for 3 months. After first visit, the severity and duration of patients' headache in two groups were followed up for 3 months. The instruments for data collection included forms for demographic characteristics, Visual Analogue Scale for measuring severity of headache, and checklists designed for following up and documentation of severity and duration of patients' headache and drug consumption.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014032717090N1**

Registration date: **2014-06-07, 1393/03/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-06-07, 1393/03/17

##### Registrant information

##### Name

Mahmoud Bakhshi

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1859 1511

##### Email address

bakhshim881@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research of Islamic Azad University of Sharoud

##### Expected recruitment start date

2009-06-24, 1388/04/03

##### Expected recruitment end date

2011-01-18, 1389/10/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of leech therapy on primary headache in patients referring to Cupping unit

## Public title

The effect of leechtherapy on headache

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criterion: diagnosis of primary headache by neurologist based on diagnostic parametres. Exclusion criteria: patients with brain tumors and other brain diseases; patients with sinusitis and anemia (Hb<10 g/dl); pregnant or breastfeeding women; patients with hemorrhagic disorders ; using anticoagulant drugs ; patients with acute medical conditions such as cardiac, renal and hepatic diseases.

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 45

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Islamic Azad University of Shahroud

##### Street address

Beside Police Station, after traveling terminal

##### City

Shahroud

##### Postal code

#### Approval date

2009-04-14, 1388/01/25

#### Ethics committee reference number

88/088

## Health conditions studied

### 1

#### Description of health condition studied

Primary headache

#### ICD-10 code

G43, G44

#### ICD-10 code description

Migraine, other headache syndromes

## Primary outcomes

### 1

#### Description

Severity of headache

#### Timepoint

Before and after intervention at first week , first month, second month and third month subsequently

#### Method of measurement

visual analogue scale

### 2

#### Description

duration of headache

#### Timepoint

Before and after intervention at first week , first month, second month and third month subsequently

#### Method of measurement

time by hours in day

## Secondary outcomes

### 1

#### Description

duration of disease

#### Timepoint

First visit

#### Method of measurement

interview

### 2

#### Description

drug consumption

#### Timepoint

Before and after intervention at first week , first month, second month and third month subsequently

#### Method of measurement

self-reporting

## Intervention groups

### 1

#### Description

Leech therapy:1-3 leeches were placed behind the patient s ear. Each session lasted approximately 30-50 minutes. in average, each patient undertook

leechtherapy, 1 to 3 session every 3 weeks.

**Category**

Other

**2**

**Description**

Drug therapy (propranolol 40 mg, Nortriptyline 50 mg or citalopram 20 mg)daily

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Cupping Center

**Full name of responsible person**

Mr Hossein Taheri

**Street address**

Opposite Traffic office, Tehran Avenue

**City**

Shahroud

**2**

**Recruitment center**

**Name of recruitment center**

Private Office

**Full name of responsible person**

Dr Babak Jalalian

**Street address**

Bahar medical building, 22 Bahman Avenue

**City**

Shahroud

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research of Islamic Azad University of Shahroud

**Full name of responsible person**

Dr Behzad Chahcandi

**Street address**

Islamic Azad University, Shahroud

**City**

Shahroud

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for research of Islamic Azad University of Shahroud

**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**

Islamic Azad University of Shahroud

**Full name of responsible person**

Mr Mahmoud Bakhshi

**Position**

Faculty member

**Other areas of specialty/work**

**Street address**

Nursing faculty, Islamic Azad University, Shahroud

**City**

Shahroud

**Postal code**

**Phone**

+98 27 3339 4342

**Fax**

**Email**

bakhshi\_mahmoud@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University of Shahroud

**Full name of responsible person**

Mr Mahmoud Bakhshi

**Position**

Master of Science

**Other areas of specialty/work**

**Street address**

Islamic Azad University, Shahroud

**City**

Shahroud

**Postal code**

**Phone**

+98 27 3339 4342

**Fax**

**Email**

bakhshi\_mahmoud@yahoo.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Islamic azad university of Shahroud

**Full name of responsible person**

Mr Mahmoud Bakhshi

**Position**

Master of science

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

No 39, Shaghayegh Avenue, Novin suburb

**City**

Shahrud

**Postal code****Phone****Fax****Email**

bakhshim881@mums.ac.ir;

bakhshi\_mahmoud@yahoo.com

**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*