Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Mahmoud Bakhshi
Name of organization / entity
Mashhad University of Medical Sciences
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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 Chancelor 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 Chancelor 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

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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