Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of manual therapies on severity and frequency of pain in patients with tension headache that does not respond to the drug

Protocol summary

Summary

Background: Headache is one of the most common neurological condition that has affect on a lot of people. Tension type headache (TTH) is one of the most common type of headache in society. Tension type headache involves myofascial and CNS factors. Myofascial activity can be a source of TTH due to trigger points. Sometime in drug therapy, the patient's body does not respond appropriately. For this reason, non-pharmacological treatments should always be considered. One of the treatments for TTH patients is manual therapy. Materials and Methods: This study is a clinical trial. The sample size was 12 people in each group. Subjects with tension type headache that do not respond to the drug will be selected. Inclusion criteria: A headache that lasts from 30 minutes to 7 days. exclusion criteria: Surgical surgery; Neck disc hernia After filling the consent forms, the samples are subdivided into two groups by random method(treatment group and control group). The treatment group receives a series of manual therapy including massage, release of myofascia , release trigger points with friction massage and cervical mobilization . The severity of pain, the number of pills, cervical range of motion and NDI questionnaire will be evaluated in these individuals.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082924149N36**
Registration date: **2017-09-26, 1396/07/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-26, 1396/07/04

Registrant information

Name

Fahimeh Kamali

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1627 1551

Email address

kamalif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Science

Expected recruitment start date

2017-09-16, 1396/06/25

Expected recruitment end date

2017-10-27, 1396/08/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of manual therapies on severity and frequency of pain in patients with tension headache that does not respond to the drug

Public title

The effect of manual therapy on patients with tension type headache that do not respond to the drug

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Headache that lasts from several minutes to several hours; According to the IHS criteria . Headache that has at least two characteristics:No

pulsating mode; Its severity is mild to moderate; Do not exacerbate daily activities such as walking and climbing the stairs; Not having nausea and vomiting and photophobia and phonophobia during the attack. Exclusion criteria: Cervical surgery; Cervical disc hernia; Pregnancy; Breastfeeding; Migraine; Severe cervical trauma; Cervical Malignancy; Rheumatism; Fibromyalgia; Cardiovascular disease; Physiotherapy and massage in the last 6 months; Temporomandibular joint disorder.

Age
From **18 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Shiraz University of Medical Science

Street address
Zand street, forward Flestin street, Central building of Shiraz University of Medical Science

City
Shiraz

Postal code
7134814336

Approval date
2017-07-18, 1396/04/27

Ethics committee reference number
IR.SUMS.REC.1396.64

Health conditions studied

1

Description of health condition studied
Tension type headache

ICD-10 code
G44.2

ICD-10 code description
Chronic tension-type headache, Episodic tension headache, Tension headache NOS

Primary outcomes

1

Description
pain intensity

Timepoint
before treatment, after treatment, 1 week after treatment

Method of measurement
Numerical rating scale pain

2

Description
Pain frequency

Timepoint
before treatment, after treatment, 1 week after treatment

Method of measurement
The number of days that patients have headache in one week

3

Description
Consumed pills

Timepoint
before treatment, after treatment, 1 week after treatment

Method of measurement
The number of pills in one week

Secondary outcomes

1

Description
Neck Disability Index

Timepoint
before treatment , after treatment , one week after treatment

Method of measurement
Score questionnaire

2

Description
Cervical range of motion

Timepoint
before treatment , after treatment , one week after treatment

Method of measurement
Goniameter

Intervention groups

1

Description
The control group does not receive manual therapy
Category
N/A

2

Description
In this study, the treatment group received a manual therapy package, including the release of the neck and shoulders fascia , cervical moblization, the release of the trigger points of the upper trapezius , sub occipital and sternocloidomastoid muscles with friction. The case group receives three sessions of treatment.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Clinic
Full name of responsible person
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Science , Faculty of Rehabilitation Sciences
Full name of responsible person
Fahimeh kamali-Sarvestani
Street address
Abiverdi St, Chmaran Ave, Shiraz, Iran
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Science , Faculty of Rehabilitation 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
Shiraz University of Medical Science
Full name of responsible person
Fahimeh Kamali-Sarvestani
Position
employee of a Shiraz University of Medical Sciences
Other areas of specialty/work
Street address
Abiverdi St, Chmaran Ave, Shiraz, Iran
City
Shiraz
Postal code
7194733669
Phone
+98 71 3626 1081
Fax
Email
negarazhdari12@gmail.com
Web page address
http://rehab.sums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Science
Full name of responsible person
Fahimeh Kamali-Sarvestani
Position
PHD
Other areas of specialty/work
Street address
Abiverdi St, Chmaran Ave, Shiraz, Iran
City
Shiraz
Postal code
7194733669
Phone
+98 71 3626 1081
Fax
Email
kamalif@sums.ac.ir
Web page address
http://rehab.sums.ac,ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Science
Full name of responsible person
Negar Azhdari
Position

Master's degree in Physiotherapy

Other areas of specialty/work

Street address

Abiverdi St, Chmaran Ave, Shiraz, Iran

City

Shiraz

Postal code

7194733669

Phone

+98 71 3626 1081

Fax

Email

negarazhdari12@gmail.com

Web page address

http://rehab.sums.ac.ir

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