

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 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

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Name of organization / entity

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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

Goniometer

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 mobilization, the release of the trigger points of the upper trapezius , sub occipital and sternocleidomastoid 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

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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