

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of cervical trigger point management by Positional Release Therapy on the central sensitization in patients with tension type headache

Protocol summary

Summary

Objective: In this study we try to determine the effectiveness of trigger point management by Positional Release Technique on central sensitization in tension type headache patients. Design: This study is a randomized clinical trial by simple sampling method. Subjects are patients with tension type headache which will be randomly divide to two treatment and control groups. Patients are blind about study groups. Setting and Conduct: The pressure pain threshold and concentration of brain metabolites will be recorded by Algometer and MRS respectively before and after treatment. Participants: 26 patients with tension type headache and any trigger points in cervical muscles will enter to the study. Intervention: Treatment group receive Positional Release therapy (PRT) on the trigger points of cervical muscles. Control group receive routine drugs. Main outcome measures: Pressure pain threshold and brain metabolite concentration.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071726674N2**

Registration date: **2016-08-23, 1395/06/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-23, 1395/06/02

Registrant information

Name

Marzieh Mohamadi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-07-31, 1395/05/10

Expected recruitment end date

2017-08-01, 1396/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cervical trigger point management by Positional Release Therapy on the central sensitization in patients with tension type headache

Public title

The effect of cervical trigger point management on tension type headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Existence more than 3 months of headache; Existence of any trigger points in cervical muscles. exclusion criteria: other types of headaches; cervical disk herniation; neurological disorders;

rheumatoid disorders; history of whiplash injury or head trauma; useage of anti-depressant and anti-anxiety drugs; complain from knee or leg pain.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization is done by blocked randomization methode

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

Street address

Zand Street

City

Shiraz

Postal code**Approval date**

2016-06-06, 1395/03/17

Ethics committee reference number

IR.SUMS.REC.1395.47

Health conditions studied**1****Description of health condition studied**

tension type headache

ICD-10 code

G44.2

ICD-10 code description

Tension-type headache

Primary outcomes**1****Description**

pressure pain threshold

Timepoint

5 weeks

Method of measurement

Algometer instrument

2**Description**

concentration of Total Choline (tCho)

Timepoint

5 weeks

Method of measurement

MRS instrument

3**Description**

concentration of N-Acetyl-Aspartate (NAA)

Timepoint

5 weeks

Method of measurement

MRS instrument

4**Description**

concentration of Creatin (Cr)

Timepoint

5 weeks

Method of measurement

MRS instrument

5**Description**

concentration of Myo-Inositol (MI)

Timepoint

5 weeks

Method of measurement

MRS instrument

6**Description**

concentration of Glx

Timepoint

5 weeks

Method of measurement

MRS instrument

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Routine treatment

Category

Treatment - Drugs

2

Description

Intervention group: Positional release Technique

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza (A) clinic

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Doctor Seyed-Basir Hashemi

Street address

Zand Street

City

Shiraz

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, Shiraz 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

School of Rehabilitation Sciences, Shiraz University of Medical Sciences

Full name of responsible person

Marzieh Mohamadi

Position

Student

Other areas of specialty/work

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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