Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 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

Shiraz University of Medical Sciences, School of Rehabilitation Sciences

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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
consentration 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
consentration 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
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Person responsible for scientific inquiries

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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