Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of cervical trigger points' management by Positional Release Therapy with routine medication in patients with tension type headache whoe has refered to Emam Reza & Shahid Faghihi clinics

Protocol summary

Summary

Background: The aim of this study was to compare the effectiveness of trigger points' management by Positional Release Therapy and routine medical therapy in treatment of tension type headache. Inclusion and exclusion criteria: patients with tension type headache and any trigger points in posterior cervical muscles will include to the study and patients with cervical disk herniation , patients who use opioid, anti anxiety and anti depressant drugs and pregnant patients will exclude from the study. Sample size: In this study there will be 30 tension type headache patients with active trigger points in posterior cervical muscles who will choose among the patients that has refered to the Emam Reza and Shahid Faghihi clinics. Intervention: 15 0f patients will enter to PRT group and 15 of them will enter to medication group. Headache frequency, intensity and duration and tablet count will record throughout the study by use of a daily headache diary. Sensitivity of trigger points will assess by numeric pain intensity (NPI) and by use of a digital force gauge (FG 5020).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204082708N4**
Registration date: **2012-04-25, 1391/02/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-04-25, 1391/02/06

Registrant information

Name

Ali Ghanbari

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1627 1551

Email address

ghanbary@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-09-20, 1391/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of cervical trigger points' management by Positional Release Therapy with routine medication in patients with tension type headache whoe has refered to Emam Reza & Shahid Faghihi clinics

Public title

Treatment of tension type headache by positional release therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: tension type headache; trigger point in posterior cervical muscles Exclusion criteria: cervical disk

herniation; usage of opioid, anti anxiety and anti depressant drugs; pregnancy

Age
No age limit

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
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
Shiraz University of Medical Sciences

Street address
Zand street

City
Shiraz

Postal code

Approval date
2010-06-22, 1389/04/01

Ethics committee reference number
الف 5253-89

Health conditions studied

1

Description of health condition studied
Tension-Type headache

ICD-10 code
G44.2

ICD-10 code description
other headache syndromes

Primary outcomes

1

Description
headache intensity

Timepoint
before & after intervention, 2 weeks after last intervention

Method of measurement
daily headache diary

2

Description
headache duration

Timepoint
before & after intervention, 2 weeks after last intervention

Method of measurement
daily headache diary

3

Description
headache frequency

Timepoint
before & after intervention, 2 weeks after last intervention

Method of measurement
daily headache diary

4

Description
Tablet count

Timepoint
before & after intervention, 2 weeks after last intervention

Method of measurement
daily headache diary

Secondary outcomes

1

Description
pain tolerance in trigger point site

Timepoint
befor & after intervention, 2 weeks after last intervention

Method of measurement
pressure algometer

2

Description
pain intensity in trigger point site

Timepoint
befor & after intervention, 2 weeks after last intervention

Method of measurement
numeric pain index

Intervention groups

1

Description

positonal release therapy which is used 2 times per week for 5 treatment sessions. in this manner that patient is lied in a position in which the muscle is relaxed.

Category

Rehabilitation

2

Description

medication with Nortriptyline 25 mg once a day and meloxicam 15 mg twice a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

rehabilitation school

Full name of responsible person

Marzieh Mohamadi

Street address

Abiverdi street

City

hiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shraz University of Medical Sciences

Full name of responsible person

Dr Gholamreza Hatam

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

Shraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr Ali Ghanbari

Position

Faculty of rehabilitation school

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