

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparative study of the effect of lumbar and cervical myofascial release on flexibility, pain and quality of life in cervicogenic headache patients

Protocol summary

2019-07-18, 1398/04/27

Study aim

studying the effect of myofascial release on cervical ROM and myofascial elasticity in cervicogenic patients, and also studies the effect of application of myofascial release in lumbar region on cervical region

Design

clinical trial with parallel groups

Settings and conduct

Myofascial release is a manual therapy technique which is focused on fascial elasticity by applying compressive and tensile forces. the place of this study is in the shahid bahonar hospital in the city of kerman

Participants/Inclusion and exclusion criteria

cervicogenic headache patients with the age between 20 and 50 and myofascial tissue stiffer than normal group; diagnosis of other types of headaches and application of physical therapy at recent 6 months

Intervention groups

1- application of myofascial release on cervical region 2- application of myofascial release on lumbar region

Main outcome variables

coefficient of elastic. range of motion of the neck, intensity of the pain, quality of life, range of motion of the lumbar region, the amount of forward head, the amount of inclination of the pelvis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190221042794N1**

Registration date: **2019-07-18, 1398/04/27**

Registration timing: **prospective**

Last update: **2019-07-18, 1398/04/27**

Update count: **0**

Registration date

Registrant information

Name

Mahdi Tavakkoli

Name of organization / entity

The University of Tarbiat Modares

Country

Iran (Islamic Republic of)

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+98 21 8288 3824

Email address

mtavakkoli@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of lumbar and cervical myofascial release on flexibility, pain and quality of life in cervicogenic headache patients

Public title

effect of myofascial release on cervicogenic headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age between 20 and 30 years suffering from CGH based on the diagnosis of specialized doctor according to

ICHD-2018-3 the tragus at least 2/5 centimeter at the anterior of vertical line the amount of lumbar flexion lesser than 35 degrees headache at least once a week in recent 2 months based on VAS the intensity of headache should be at least 5 BMI between 18 to 24 and 24 to 30 the elastic coefficient of the cervical region should be higher than the normal group

Exclusion criteria:

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

non informing the patient the groups and their intervention

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of tarbiat modares university of tehran

Street address

No. 9, Shahid Shirvani Ave., jomhuri Eslami Blvd.

City

Kerman

Province

Kerman

Postal code

7618937773

Approval date

2019-01-27, 1397/11/07

Ethics committee reference number

IR.Modares.Rec.1397.238

Health conditions studied

1

Description of health condition studied

cervicogenic headache

ICD-10 code

G44.89

ICD-10 code description

Other headache syndrome

Primary outcomes

1

Description

Elastic Coefficient

Timepoint

2 weeks before the intervention, before the intervention, after the intervention

Method of measurement

sonography apparatus

Secondary outcomes

1

Description

cervical range of motion

Timepoint

2 weeks before the intervention, before the intervention, after the intervention

Method of measurement

goniometer

2

Description

intensity of the pain

Timepoint

2 weeks before the intervention, before the intervention, after the intervention

Method of measurement

visual analogue scale

3

Description

quality of life

Timepoint

2 weeks before the intervention, before the intervention, after the intervention, 4 weeks after the intervention

Method of measurement

Headache Impact Test with 6 questions (HIT6)

4

Description

range of motion of lumbar flexion

Timepoint

2 weeks before the intervention, before the intervention, after the intervention

Method of measurement

flexible ruler

5

Description

amount of forward head

Timepoint

2 weeks before the intervention, before the intervention,
after the intervention

Method of measurement

ruler

6

Description

amount of inclination of the pelvis

Timepoint

2 weeks before the intervention, before the intervention,
after the interventio

Method of measurement

goniometer

Intervention groups

1

Description

Intervention group: myofascial release of lumbar region

Category

Rehabilitation

2

Description

Intervention group: myofascial release of cervical region

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar hospital

Full name of responsible person

Farid Bahrpeyma

Street address

Sepah Ave.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

tarbiat modares university

Full name of responsible person

yaaghub fathollahi

Street address

Jalal AleAhmad, Nasr bridge

City

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14115-111

Phone

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Email

pres@modares.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

tarbiat modares university

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

tarbiat modares university

Full name of responsible person

farid bahrpeyma

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available