

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

###### Phone

+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**

Kerman

##### **Province**

Kerman

##### **Postal code**

7613747181

##### **Phone**

+98 34 3223 5011

##### **Email**

mahdi\_tavakkoli817@yahoo.com

## **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**

Tehran

##### **Province**

Tehran

##### **Postal code**

14115-111

##### **Phone**

+98 21 82880

##### **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

### Contact

**Name of organization / entity**

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**Full name of responsible person**

farid bahrpeyma

**Position**

Associate Professor

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Ph.D.

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## Person responsible for updating data

### Contact

**Name of organization / entity**

The University of Tarbiat Modares

**Full name of responsible person**

Mahdi Tavakkoli

**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Phone**

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**Fax****Email**

m\_tavakkoli@modares.ac.ir

## 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