# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## The effect of myofascial release and joint mobilization based on diagnostic sub group, on headache index, rang of motion, thickness of upper cervical muscles and neck disability index in cervicogenic headache subjects

## Protocol summary

**Study aim**

In-group and between group comparation of the effect of mobilization, myofascial release and routine treatment on the improvement of the headache index, on the thickness of the muscles of the upper cervical region, on the increase of the range of motion of the head and neck, on the improvement of the neck disability index in people with headaches of cervical origin Before and after treatment.

**Design**

This study will be conducted as a double-blind clinical trial with two intervention groups and two control groups. The first and second groups of intervention will respectively include people whose headache is caused by cervical origin with diagnosis of joint damage and cervical origin by soft tissue damage. The two control groups also have the mentioned characteristics, which are included in the control groups by chance.

**Settings and conduct**

The study is conducted in the rehabilitation physiotherapy clinic of Iran University of Medical Sciences and a private clinic.

**Participants/Inclusion and exclusion criteria**

People who have cervicogenic headaches IHS diagnostic criteria and physical test. include Flexion-rotation test, craniocervical flexion test, passive accessory intervertebral movement test, SCM pressure pain test, mastoid pressure pain test.

**Intervention groups**

Myofascial release + Conventional treatment. Joint mobilization + Conventional treatment. Conventional treatment

**Main outcome variables**

Age sex Headache frequency, duration, severity Headache index The range of motion of the head in flexion and extension Head and neck range of motion in flexion and extension Range of motion of the neck in bending to the right and left The range of motion of the head and neck when turning to the right and left Neck disability index questionnaire Headache disability questionnaire Muscle thickness in ultrasound Mobilization treatment group Myofascial treatment group Routine treatment group

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20240130060862N1**
Registration date: **2024-07-27, 1403/05/06**
Registration timing: **registered_while_recruiting**

Last update: **2024-07-27, 1403/05/06**
Update count: **0**

**Registration date**

2024-07-27, 1403/05/06

**Registrant information**

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**Name of organization / entity**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2024-05-30, 1403/03/10
**Expected recruitment end date**
2024-09-20, 1403/06/30
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The effect of myofascial release and joint mobilization based on diagnostic sub group, on headache index, rang of motion, thickness of upper cervical muscles and neck disability index in cervicogenic headache subjects

**Public title**
The effect of myofascial release and joint mobilization in cervicogenic headache subjects
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
1. Subjects who has cervicogenic headache based on international headache society diagnostic criteria and reliable physical tests include flexion rotation test. Craniocervical flexion test. passive accessory intervertebral movement test. mastoid pressure pain test and sternocleidomastoid pressure pain test. 2. Subjects in 18-55 years old. 3. At least a history of three months of headache and recurrence once a month. 4. Having reading and writing literacy to write the questionnaire
**Exclusion criteria:**
1. Neurological problems of neck or other parts except headache. 2. Rheumatoid problems of spondylosis and severe degenerative changes of the neck. 3. Any history of head or neck surgery confirmed by a doctor. 4. Alar ligament instability or vertebrobasilar artery disorder. 5. History of any fracture in cervical or upper thoracic vertebrae. 6. Pregnancy 7. Thoracic scoliosis with Rib hump more than 8 mm. 8. Neonatal torticollis 9. General health problems such as hemophilia, diabetes, lung diseases, metabolic diseases and any history of cancer. 10. Mental disorders diagnosed by a psychiatrist. Like depression with drug use. 11. Receiving physiotherapy, chiropractic, osteopathy, massage therapy or other treatments in the neck or upper thoracic region recently or in the last three months. 12. Consuming caffeine less than 4 hours before the primary test. 13. Drug addiction 14. Having a BMI above 30. 15. Disruption in the treatment process and failure to complete 10 treatment sessions for any reason. 16. Difficulty in communicating effectively
**Age**
From **18 years** old to **55 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**
Target sample size: **88**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this study, randomization is done according to the type of diagnosis (joint disorder, soft tissue disorder). volunteers are evaluated before randomization, and after the main cause of the problem is determined, they will be randomly assigned to one of the two interventions or control groups specific to their diagnosis. Considering that there are two subgroups in each intervention group, the treatment performed will be specific for one of the subgroups and not for the other subgroup. In each group, which people are placed in which subgroup is a random process.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
In this study, the participants are blind of their groupings. Considering that there are 2 subgroups in each group, the therapist is blind of which subgroup each candidate is in. In this study, the outcome analyzer is blind of grouping and the group of each candidate.
**Placebo**
Used
**Assignment**
Factorial
**Other design features**
The way of grouping is based on diagnosis and there is a diagnostic sub-group in each group. For the subgroups in each group, the same treatment will done.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
ethics committee of Iran university of medical sciences
**Street address**
No 1, hosseynieh alley, dolat Ave, tehran
**City**
Tehran
**Province**
Tehran
**Postal code**
1951633111
**Approval date**
2024-05-11, 1403/02/22
**Ethics committee reference number**
IR.IUMS.REC.1403.128

## Health conditions studied

### 1

**Description of health condition studied**
cervicogenic headache
**ICD-10 code**
XIII
**ICD-10 code description**
disease of musculoskeletal system and connective tissue

## Primary outcomes

### 1

**Description**
Headache index questionnaire include frequency, duration and intensity of headache
**Timepoint**
Before the intervention and after completing 10 intervention sessions and 3 months after the last intervention session
**Method of measurement**
Questionnaire

### 2

**Description**
Headache disability inventory questionnaire
**Timepoint**
Before the intervention and after completing 10 intervention sessions and 3 months after the last intervention session
**Method of measurement**
Questionnaire

### 3

**Description**
Neck pain and disability scale questionnaire
**Timepoint**
Before the intervention and after completing 10 intervention sessions and 3 months after the last intervention session
**Method of measurement**
Questionnaire

### 4

**Description**
Upper cervical muscle thickness
**Timepoint**
Before the intervention and after 5 session of intervention and after completing 10 intervention sessions
**Method of measurement**
Musculoskeletal sonography

## Secondary outcomes

### 1

**Description**
Head and neck range of motion in 3 plan of movement
**Timepoint**
Before the intervention and after the completion of 5 intervention sessions and after the completion of 10 intervention sessions
**Method of measurement**
Goniometry based on degrees

## Intervention groups

### 1

**Description**
First Intervention group: joint dysfunction treatment including joint mobilization technique based on diagnosed dysfunction which will be performed by a physiotherapist for ten sessions on a average day.
**Category**
Treatment - Other

### 2

**Description**
Second Intervention group: soft tissue dysfunction treatment include myofascial technique and ischemic compression on muscles which related on diagnosed dysfunction which will be performed by a physiotherapist for ten sessions on a average day.
**Category**
Treatment - Other

### 3

**Description**
Control group: Routine treatment based on guideline which mention on reference part which will be performed by a physiotherapist for ten sessions on a average day.
**Category**
Treatment - Other

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Orthopedic clinic of rehabilitation school of Iran university of medical sicences
**Full name of responsible person**
Mohammad Akbari
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## Sponsors / Funding sources

**1**

**Sponsor**

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**Full name of responsible person**

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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Iran University of Medical Sciences

**Proportion provided by this source**

20

**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**

Iran University of Medical Sciences

**Full name of responsible person**

Mohammad Akbari

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Not applicable
**Data Dictionary**
Not applicable
**Title and more details about the data/document**
All data is potentially shareable after de-identifying individuals
**When the data will become available and for how long**
The access period starts 6 months after the results are published
**To whom data/document is available**
It will be available for researchers working in academic and scientific institutions
**Under which criteria data/document could be used**
The use of data is free if it is for public benefit and with the reference of the source.
**From where data/document is obtainable**
To receive data, applicants can refer to any of the researchers or contact the contact number or email of the person in charge
**What processes are involved for a request to access data/document**
After registering the application, the process of providing the data will be explained to the applicant and it will be delivered to her within 2 working weeks.(feminine)
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