Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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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Mohammad amir Bonakdar Tehrani

Name of organization / entity

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Email address

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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
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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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School Rehabilitation, Tavanbakhshi alley, Shahnazari ave, Madar Squire, Tehran
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Fax

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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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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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