Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of suboccipital muscles release, using Instrument Assisted Soft Tissue Mobilization technique on pain, range of motion of the upper cervical region, function of the deep flexor muscles of the neck, sense of force, balance and neck disability index in cervicogenic headache subjects

Protocol summary

Study aim

Investigating the effect of suboccipital muscles release, on pain, range of motion of the upper cervical region, function of the deep flexor muscles of the neck, sense of force, balance and neck disability index in cervicogenic headache subjects

Design

Individuals with cervicogenic headaches will be randomly assigned to two equal groups.One group will receive suboccipital muscle release using an instrument along with routine physiotherapy,the other group will receive a sham instrument along with routine physiotherapy. this study will be conducted as a pilot on 10 participants to determine the sample size.

Settings and conduct

This study will be conducted at the Physiotherapy Clinic of Shahid Beheshti University of Medical Sciences. In this study, a stainless-steel instrument will be used for the release of the suboccipital muscles in individuals with cervicogenic headache. Prior to entering the study, all participants will be informed, through the informed consent form, about the existence of two study groups and the possibility of being randomly assigned to either group. In addition, all measurements will be performed by a blinded assessor who is unaware of the participants' treatment group.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having diagnostic criteria for cervicogenic headache confirmed by a neurologist. Exclusion Criteria: Inability to tolerate study interventions.

Intervention groups

1)Suboccipital muscle release group using Instrument Assisted Soft Tissue Mobilization tools Along with routine physiotherapy 2)Sham Suboccipital muscle release group Along with routine physiotherapy

Main outcome variables

Pain intensity; pain frequency; duration of pain; range of motion of the upper cervical region; function of the deep flexor muscles of the neck; sense of force; balance; Neck disability index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231009059664N1**
Registration date: **2026-10-06, 1405/07/14**
Registration timing: **prospective**

Last update: **2026-10-06, 1405/07/14**
Update count: **0**

Registration date

2026-10-06, 1405/07/14

Registrant information

Name

Shideh Badeleh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date
2026-10-12, 1405/07/20
Expected recruitment end date
2026-12-11, 1405/09/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of suboccipital muscles release, using Instrument Assisted Soft Tissue Mobilization technique on pain, range of motion of the upper cervical region, function of the deep flexor muscles of the neck, sense of force, balance and neck disability index in cervicogenic headache subjects

Public title
The effect of suboccipital muscles release, using Instrument Assisted Soft Tissue Mobilization technique, in cervicogenic headache subjects
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having diagnostic criteria approved by a neurologist Headache severity in VAS ≥ 3 Neck Disability Index score ≥ 10 Exacerbation of headache by external pressure on the suboccipital muscles
Exclusion criteria:
Physiotherapy treatment for headache in the last 6 months History of neck and shoulder surgery History of diagnosis of primary headaches Taking drugs that cause dizziness and balance disorder Vision, vestibular and orthopedic problems affecting balance Cognitive and memory problems Contraindications for using the muscle release tool
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Following confirmation of the patient's eligibility (based on the inclusion criteria) and obtaining informed consent, baseline assessments including age and BMI will be performed to determine the relevant stratum. The block randomization list (with blocks of 4, comprising six possible sequences: AABB, ABAB, ABBA, BBAA, BABA, BAAB) will be generated in advance, separately for each stratum, by an independent individual who has no role in the visits, treatment, or assessment of patients. (A represents the first group and B represents the second group.) The result of this pre-determined allocation is placed in opaque, sealed envelopes, numbered sequentially in order of enrollment. When each eligible patient enters the study, the enrolling researcher (who has no knowledge of the content of the randomization list) opens the next envelope corresponding to that patient's stratum, in order, and the patient is assigned to the IASTM or Sham IASTM group according to the code inside the envelope. In this way, patients enter the randomization list sequentially, with no possibility of predicting the assigned group before the envelope is opened, and the process of sequence generation (by the independent individual) is kept completely separate from the process of allocation implementation (by the enrolling researcher).
Blinding (investigator's opinion)
Double blinded
Blinding description
All study measurements are performed by a blind examiner who is unaware of the conditions of the subjects, during the study, patients will remain unaware of which specific intervention (real or sham) they are receiving
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
6th floor,Shahid Beheshti University of Medical Sciences and Healthcare Services, Arabi Street,Shahid Chamran Highway,Tehran
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Tehran
Postal code
1985717443
Approval date
2023-09-12, 1402/06/21
Ethics committee reference number
IR.SBMU.RETECH.REC.1402.321

Health conditions studied

1

Description of health condition studied
Cervicogenic headache
ICD-10 code
G44.8
ICD-10 code description
Other specified headache syndromes

Primary outcomes

1

Description
intensity of pain
Timepoint
before the start of the intervention and immediately after 4 weeks of the intervention
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Neck disability index
Timepoint
before the start of the intervention and immediately after 4 weeks of the intervention
Method of measurement
Neck disability index questionnaire

2

Description
Headache frequency
Timepoint
before the start of the intervention and immediately after 4 weeks of the intervention
Method of measurement
by questionnaire

3

Description
Headache duration
Timepoint
before the start of the intervention and immediately after 4 weeks of the intervention
Method of measurement
by questionnaire

4

Description
range of motion of the upper cervical region
Timepoint
before the start of the intervention and immediately after 4 weeks of the intervention
Method of measurement
IMU sensor

5

Description
function of the deep flexor muscles of the neck
Timepoint
before the start of the intervention and immediately after 4 weeks of the intervention
Method of measurement
Dynamometer and pressure biofeedback

6

Description
balance
Timepoint
before the start of the intervention and immediately after 4 weeks of the intervention
Method of measurement
forceplate

7

Description
sense of force
Timepoint
before the start of the intervention and immediately after 4 weeks of the intervention
Method of measurement
Dynamometer

Intervention groups

1

Description
Intervention group: Release of suboccipital muscles,using Instrument Assisted Soft Tissue Mobilization technique and routine physiotherapy.in this group, in addition to routine physical therapy, steel tools are used to mobilize soft tissue and release of suboccipital muscles.The instrument is placed on the muscle at an angle of 45 degrees and small strokes are performed for 30 seconds to one minute by the beveled edge by applying pressure along the entire length of the suboccipital muscles.routine physical therapy includes TENS and exercise therapy. The intervention is carried out for 4 weeks and 2 sessions per week
Category
Rehabilitation

2

Description
Control group: Sham Instrument Assisted Soft Tissue Mobilization technique of suboccipital muscles and routine physiotherapy.In this group, in addition to routine physiotherapy, steel tools are used as a sham.Small strokes are performed on the entire length of the suboccipital muscles superficially, without applying pressure , for 30 seconds to one minute by the beveled edge.routine physical therapy includes TENS and exercise therapy. The intervention is carried out for 4 weeks and 2 sessions per week

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical training centers affiliated with the university
Full name of responsible person
shideh badeleh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
shideh badeleh
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Shahid Beheshti University of Medical Sciences Faculty of Rehabilitation Sciences, Imam Hossein Square, Damavand Street
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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
Shahid Beheshti University of Medical Sciences
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
shideh badeleh
Position
PhD student
Latest degree
Master
Other areas of specialty/work
Physiotherapy
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Contact

Name of organization / entity
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Latest degree
Master

Other areas of specialty/work
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Email

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