Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Investigation of the Effect of upper cervical Mobilization on Migraine headaches by functional Magnetic Resonance Imaging (fMRI) findings with Trigeminal nerve stimulation

Protocol summary

Study aim

The effect of upper cervical mobilization in migraine patients on brain fMRI findings and intensity, frequency and duration of headache attacks before and after treatment.

Design

Sham controlled clinical trial with a parallel group design of 30 patients, Concealed, randomized, blinded, follows for 12 weeks.

Settings and conduct

Interventions are done by the researcher at Doran Hospital in Shiraz, Radiology Technician and analyzer , assessor and the statistics group are unaware of how they are puts in the groups

Participants/Inclusion and exclusion criteria

Inclusion criteria : 20 to 55 years; Diagnosis of Episodic Migraine without aura by a neurologist; attacks at least 2-5 per month; At least one year ; No change in medication in the last three months Exclusion criteria: Malignancy; Diabetes; Rheumatism; Peripheral neuropathy, Fibromyalgia, Osteoporosis, Surgical history, Radiculopathy, Cervical spine disorders in simple graphic image and its soft tissue components (disc or soft tissue elements); Nerve block or non-drug treatments in the last 6 months; Severe physical / psychiatric / internal limitations (blood pressure, heart disease) / eye and ear diseases, normal or surgical menopause, pregnancy, lactation; Headache due to drug overdose, other primary or secondary headaches; Positive response to Tectorial membrane, Alar and Transverse ligaments tests; Cases of not entering the MRI scanner.

Intervention groups

intervention group Mobilization of the upper cervical spine (grade 3 Maitland) in the form of extension, lateral flexion and rotation glides In supine position control group Sham treatment (very gentle massage at neck)

Main outcome variables

Findings of fMRI images Average severity, duration and frequency of headaches Questionnaires scores (HIT-6), (MIDAS), (VAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170524034119N3**
Registration date: **2022-07-03, 1401/04/12**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-03, 1401/04/12**
Update count: **0**

Registration date

2022-07-03, 1401/04/12

Registrant information

Name

Jaleh Farahmand Farzaneh

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-07-06, 1401/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the Effect of upper cervical Mobilization on Migraine headaches by functional Magnetic Resonance Imaging (fMRI) findings with Trigeminal nerve stimulation

Public title

"Investigation of the Effect of cervical Mobilization on Migraine by functional Magnetic Resonance Imaging (fMRI) findings"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of episodic migraine without aura by a neurologist The minimum duration of the disease is one year Number of attacks at least 2-5 attacks per month No change in medications in the last three months

Exclusion criteria:

Positive response to VBI tests of Alar ligament, Transverse ligament, Tectorial membrane Any abnormal signs in the structural condition of the cervical spines in X-Ray findings Symptoms of Vertebrobasilar Insufficiency (VBI) Malignancy, Diabetes, Rheumatoid disease, peripheral neuropathy, Fibromyalgia, Osteoporosis, history of surgery, radiculopathy, disc dysfunction or soft tissue elements in the neck Performing Nerve Block or non-drug treatment (Physiotherapy, Manual therapy, Acupuncture, etc.) in the last 6 months

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The Randomization method will be Simple, Classified and Limited in such a way that: first the individuals are selected according to the inclusion and exclusion criteria, then a total volume of closed envelopes allocation concealment containing numbers 1 and 2 including 15 numbers 1 related to the intervention group and 15 numbers 2 related to the sham group are placed in a lottery container and then the envelopes are removed from the container without replacement.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study: Patients, Radiologist and Researcher analyzing the fMRI data will be blind to group assignments.

Placebo

Used

Assignment

Parallel

Other design features

The effect of cervical spines mobilization on fMRI findings

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Tarbiat Modares University

Street address

NO.46, Afifabad Ave.,Ghasrdasht

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Approval date

2022-03-08, 1400/12/17

Ethics committee reference number

IR.MODARES.REC.1400.349

Health conditions studied

1

Description of health condition studied

Migraine

ICD-10 code

G43.0

ICD-10 code description

Migraine without aura

Primary outcomes

1

Description

"Brain fMRI findings"

Timepoint

before the intervention, 5 weeks after the start of the intervention (after the intervention)

Method of measurement

fMRI image analysis

2

Description

"Midas Disability Questionnaire Score (MIDAS)"

Timepoint

Before the intervention and 12 weeks after the last intervention session

Method of measurement

"The MIDAS (Migraine Disability Assessment) questionnaire"

3

Description

"Mean severity of attacks in people with migraine (VAS)"

Timepoint

Before the intervention, after ten session intervention and 12 weeks after the last intervention session

Method of measurement

The visual analog scale (VAS)

4

Description

Questionnaire score of the impact of headache on the life of people with migraine (HIT-6)

Timepoint

Before the intervention, after ten session intervention and 12 weeks after the last intervention session

Method of measurement

Headache Impact Test-6 (HIT-6) for Migraine Patients questionnaire

Secondary outcomes

1

Description

Active cervical flexion movement

Timepoint

Before the intervention and after the last intervention session

Method of measurement

iPhone inclinometer app

2

Description

Active cervical extension movement

Timepoint

Before the intervention and after the last intervention session

Method of measurement

iPhone inclinometer app

3

Description

Active cervical lateral flexion movement

Timepoint

Before the intervention and after the last intervention session

Method of measurement

iPhone inclinometer app

4

Description

Active cervical rotation movement

Timepoint

Before the intervention and after the last intervention session

Method of measurement

iPhone inclinometer app

5

Description

Flexion-rotation test (FRT)

Timepoint

Before the intervention and after the last intervention session

Method of measurement

iPhone compass app

6

Description

Head postural assessment (FHP)

Timepoint

Before the intervention and after the last intervention session

Method of measurement

Photographic images by Canon IXY 12 digital camera from lateral and sagittal plane in standing position with measurement of craniovertebral angle (CVA) showing the position of the head in relation to the C7 vertebra.

Intervention groups

1

Description

Intervention group: Mobilization of the first and second and third cervical spine in the form of extension, rotation and lateral flexion glides to both sides, which is done by the radial side of the index finger. A total of 15 movements. Each movement is repeated 30 times with a frequency of 1 to 2 Hz. The duration of each treatment session is approximately 20 to 30 minutes, which will be done twice a week, a total of 10 sessions (5 weeks).

Category

Rehabilitation

2

Description

Control group: The intervention is sham (the therapist holds the patient's head in his hands for 30 minutes and applies a very gentle massage every few minutes). Twice a week, a total of 10 sessions (5 weeks) will be done.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Doran Hospital

Full name of responsible person
Morteza Ghanbari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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
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Position
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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