

# 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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Full name of responsible person**

Jaleh Farahmand Farzaneh

**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

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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