

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Effect of Upper Cervical Spine Manual Therapy on the Clinical and Physical Signs and Symptoms, Disability, and Electrophysiological Findings in the Migraineur Subjects with Neck Pain

Protocol summary

Study aim

The aim of this study is to evaluate the effect of upper cervical spine therapy on clinical and physical symptoms, disability and electrophysiological findings in people with migraine with neck pain.

Design

The subjects will be examined to diagnose migraines and upper cervical spine disorders. The subjects will be randomly divided into groups 1 to 4 (group 4 will include migraines without neck pain). Then electrophysiological assessments will be performed. At the end of the electrophysiological, physical, and disability assessments, individuals will be given a form to record headache-free days, headache days, headache intensity, and headache days and medications in the next month. Then people will be intervened in 4 sessions. After the end of the interventions, all evaluations will be done again so that the changes resulting from the interventions can be measured. The data from the evaluations will be compared in each group. A group of people without migraine and neck pain will also be included in the study for electrophysiological comparison with people with migraine with neck pain.

Settings and conduct

Headache Clinic at Sina Hospital and Faculty of Medical Sciences, Tarbiat Modares University

Participants/Inclusion and exclusion criteria

Subjects with migraine in the age range of 18 to 50 years will be included in the study.

Intervention groups

Group 1: Manual therapy plus classical drug treatment
Group 2: Sham manual therapy plus classical drug treatment
Group 3: Classic drug therapy group
Group 4: Migraine group without neck pain (without manual therapy intervention)
Group 5: Control group: healthy subjects of the same age (without migraine and neck pain)

Main outcome variables

Headache frequency, Headache intensity, Headache duration, medications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160621028567N2**

Registration date: **2021-03-10, 1399/12/20**

Registration timing: **prospective**

Last update: **2021-03-10, 1399/12/20**

Update count: **0**

Registration date

2021-03-10, 1399/12/20

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 3559

Email address

m.jafarii@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-10-07, 1400/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Upper Cervical Spine Manual Therapy on the Clinical and Physical Signs and Symptoms, Disability, and Electrophysiological Findings in the Migraineur Subjects with Neck Pain

Public title
Effect of Cervical Spine Manual Therapy on the Electrophysiological Findings in the Migraineur Subjects with Neck Pain

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Migraine according to IHS criteria at least three days a month Neck pain (more than 30% NDI and at least one symptomatic segment according to PAIVMs in the upper cervical spine) with migraine Age between 18 and 50 years
Exclusion criteria:
Other primary or secondary headaches Other neurological diseases Severe physical / psychiatric limitations Ear disorders Medication Overuse Headache Systemic diseases such as fibromyalgia or rheumatoid arthritis Vertebrobasilar insufficiency / atherosclerosis of cervical arteries Cervical spine instability and alar and transverse ligament defects Nerve blocks in the last 6 months Neck and shoulder physiotherapy treatments in the last 6 months Malignancies

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible individuals will be randomly assigned to groups 1 through 4 after the initial evaluation by a researcher who is not involved in the evaluations. In order to preserve allocation concealment, the subjects will be included in the study in 1:1 ratio by a random block of 2 using a sealed envelope.

Blinding (investigator's opinion)
Double blinded

Blinding description
Assignments to study groups will be kept from the analyzer researcher, assessor researcher, and the participants. In order to blind the subjects, the sham

intervention will be performed with the same force, palpation, and duration as the main intervention. Another independent researcher will perform statistical analysis and result interpretation. For obvious reasons, healthcare providers cannot be kept blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Tarbiat Modares University
Street address
Jalal AleAhmad
City
Tehran
Province
Tehran
Postal code
1411713116
Approval date
2020-11-09, 1399/08/19
Ethics committee reference number
IR.MODARES.REC.1399.120

Health conditions studied

1

Description of health condition studied
Migraine
ICD-10 code
G43
ICD-10 code description
Migraine

2

Description of health condition studied
Neck Pain
ICD-10 code
G54.2
ICD-10 code description
Cervical root disorders, not elsewhere classified

Primary outcomes

1

Description
Headache Intensity

Timepoint

At the beginning of the study, one month after end of interventions

Method of measurement

Designed form for recording the clinical characteristics of headache

2

Description

Headache Frequency

Timepoint

At the beginning of the study, one month after end of interventions

Method of measurement

Designed form for recording the clinical characteristics of headache

3

Description

Pain killer medications

Timepoint

At the beginning of the study, one month after end of interventions

Method of measurement

Designed form for recording the clinical characteristics of headache

4

Description

Headache Duration

Timepoint

At the beginning of the study, one month after end of interventions

Method of measurement

Designed form for recording the clinical characteristics of headache

Secondary outcomes

1

Description

Wave I latency

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

Brain Auditory Evoked Response

2

Description

Wave II latency

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

Brain Auditory Evoked Response

3

Description

Wave III latency

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

Brain Auditory Evoked Response

4

Description

Wave IV latency

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

Brain Auditory Evoked Response

5

Description

Wave IV latency

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

Brain Auditory Evoked Response

6

Description

I-III interpeak latency

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

Brain Auditory Evoked Response

7

Description

III-IV interpeak latency

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

Brain Auditory Evoked Response

8

Description

I-IV interpeak latency

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

Brain Auditory Evoked Response

9

Description

R1 latency

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

Blink Reflex

10**Description**

R2 latency

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

Blink Reflex

11**Description**

R2 contralateral latency

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

Blink Reflex

12**Description**

Cervical flexion range of motion

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

iPhone compass application

13**Description**

Cervical extension range of motion

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

iPhone compass application

14**Description**

Cervical right rotation range of motion

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

iPhone compass application

15**Description**

Cervical left rotation range of motion

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

iPhone compass application

16**Description**

Cervical right lateral flexion range of motion

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

iPhone compass application

17**Description**

Cervical left lateral flexion range of motion

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

iPhone compass application

18**Description**

Flexion-rotation test

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

iPhone compass application

19**Description**

Manual examination of upper cervical spine joints

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

Manual

20**Description**

Visual examination of upper cervical subluxation

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

Visual

21**Description**

Headache Impact Test score

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

Persian HIT-6 questionnaire

22

Description

Neck Disability Index Score

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

Persian NDI questionnaire

23

Description

Central Sensitivity Index score

Timepoint

At the beginning of the study, one month after the end of the study

Method of measurement

Persian CSI questionnaire

Intervention groups

1

Description

Intervention group: upper cervical spine manual therapy in 4 sessions. To perform manual therapy, the patient will be in a supine position and the physiotherapist will stand above the patient. The physiotherapist will then place his or her pointer finger on the articular processes of the target segment (C1-C2). The other fingers of the physiotherapist will be spread over the patient's neck. The physiotherapist will then apply 5 times a 30-second nonthrust pressure to the C0 / C1 and C1 / C2 articular processes in a posterior-anterior displacement, lateral displacement, or rotation, in a direction that does not reproduce the headache symptoms. .

Category

Rehabilitation

2

Description

Intervention group: Sham upper cervical manual therapy in 4 sessions. The sham manual therapy will be performed as follows: the physiotherapist's hands will be in wide and non-specific contact with the person's neck, and the therapy will be a fake maneuver of pushing the vertebrae at a low speed and amplitude in a non-therapeutic direction.

Category

Placebo

3

Description

Intervention group: without manual therapy interventions

Category

Other

4

Description

Intervention group: Migraine group without neck pain (without manual therapy intervention)

Category

N/A

5

Description

Control group: : Control group: healthy subjects of the same age (without migraine and neck pain)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Mansoureh Togha

Street address

Emam Khomeyni Ave.

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Tehran

Province

Tehran

Postal code

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Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Mohammad Taghi Ahmadi

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1411713116

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Email

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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
Tarbiat Modares University
Full name of responsible person
Farid Bahrpeyma
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
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Province
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Person responsible for scientific inquiries

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Person responsible for updating data

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Tarbiat Modares University
Full name of responsible person
Mehdi Jafari
Position
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Latest degree
Master
Other areas of specialty/work
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Postal code
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m.jafarii@modares.ac.ir

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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
a part of data
When the data will become available and for how long
6 months after publications
To whom data/document is available
Researchers
Under which criteria data/document could be used
for treatment and research goals
From where data/document is obtainable
Farid Bahrpeyma
What processes are involved for a request to access data/document
Confirmation of advisor professors

Comments