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: Ŝham 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 t 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
Postal code
1136746911
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+98 21 6634 8500
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hosp_sina@sina.tums.ac.ir

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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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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Full name of responsible person
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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
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