Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Pain Neurophysiology Education in the treatment of Cervicogenic headache: A randomized clinical trial

Protocol summary

Study aim
The aim of this study was to evaluate the effect of neurophysiological pain education on the treatment of people with neck headache and compare it with conventional physiotherapy.

Design
In this study, a parallel single-blind clinical trial of 30 patients with headache of cervical origin participates Which are randomly divided into experimental and control groups by blocking method.

Settings and conduct
This study will be performed on patients with cervicogenic headache referred to neurology clinics and physiotherapy centers dependent to Isfahan Medical University.In this study, evaluators are blind to groups.

Participants/Inclusion and exclusion criteria
This study was performed on patients with headache of cervical origin referred to internal neurology clinics and physiotherapy affiliated to Isfahan University of Medical Sciences who are eligible for inclusion in the study.

Intervention groups
Treatment in the Pain Neurophysiology Education Group: it will be easy to explain using simple methods such as presentation with PowerPoint slides, pain transfer methods over 4 one hour sessions and one session per week. will be given. Conventional Physical Therapy: TENS is used to relieve pain and ultrasound, as well as exercise therapy in both groups.

Main outcome variables
Headache severity, headache frequency, headache duration,Headache Disability Index, Pain Catastrophizing Scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200101045970N2**

Registration date: **2020-09-30, 1399/07/09**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-30, 1399/07/09**

Update count: **0**

Registration date

2020-09-30, 1399/07/09

Registrant information

Name
Ehsan Ghasemi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3669 3089

Email address
eghasemi@rehab.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-25, 1399/07/04

Expected recruitment end date

2021-03-09, 1399/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Pain Neurophysiology Education in the treatment of Cervicogenic headache: A randomized clinical trial

Public title

The effect of Pain Neurophysiology Education in the

treatment of Cervicogenic headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Unilateral headache that spreads to the frontotemporal region. Pain exacerbation associated with movement or inappropriate neck postures. Moderate to severe non-pulsatile pain based on Numeric Rating Pain Scale not lower than grade 2 Enough reading and writing skills are also a requirement for inclusion.

Exclusion criteria:

Neck Radiculopathy History of neck injury Any other neck pain agent, including osteoarthritis History of cervical trigger point treatment by manual or dry needle treatment over the past 6 months Cognitive disorders Previous history of primary headache diagnosis (such as migraine and tension headache) Use of painkillers during treatment Previous history of neck or shoulder surgery Failure to co-operate

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, due to the small number of samples, in consultation with a statistician, it was decided to use the random blocking method. Blocking is usually used to balance the number of samples assigned to each of the groups studied. Statistics expert using the website https://www.sealedenvelope.com/simple-randomiser/v1/lists 15 blocks of 2 were designed considering that we had 2 groups. Divides patients according to this table is unaware of the study.

Blinding (investigator's opinion)

Single blinded

Blinding description

Assessments are performed by a person who is unaware of the groups. After completing the questionnaires, the subjects were randomly divided into two groups with block method by one person who was unaware of the study

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan Medical University

Street address

Hezar Jrib

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2020-08-04, 1399/05/14

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.301

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

pain intensity

Timepoint

Before and after treatment and one month follow up

Method of measurement

Visual Analog Scale

2

Description

Pain frequency

Timepoint

Before and after treatment and one month follow up

Method of measurement

Questionnaire

3

Description

Pain Duration

Timepoint

Before and after treatment and one month follow up

Method of measurement

Questionnaire

Secondary outcomes

1

Description
Headache Disability Inventory
Timepoint
Before and after treatment and one month follow up
Method of measurement
Headache Disability Inventory

2

Description
Pain Catastrophizing rate
Timepoint
Before and after treatment and one month follow up
Method of measurement
Pain Catastrophizing Scale

Intervention groups

1

Description
Intervention group: Pain Neurophysiology Education: This method is taught to patients by the student. In the pain neurophysiology group, the training will be such that using simple methods such as presenting with PowerPoint slides, pain transfer methods will be explained in 4 sessions of one hour and one session per week in a simple way. Pain neurophysiology training based on the book Explain pain supercharged by G.L. Mosely and D.S. It will be Butler. This training includes explanations of the origin of acute pain in the nervous system, how to change acute pain to chronic, central sensitivity, the role of the brain in perceiving pain, psychosocial factors affecting pain and cognitive and behavioral reactions related to pain and pain management. There is no reference to the anatomy and mechanics of the neck in these sessions.
Category
Treatment - Other

2

Description
Control group: Conventional Physiotherapy: This method is applied by a physiotherapist in the physiotherapy department. In this group, for 10 sessions, use Conventional TENS with a frequency of 100 Hz with a duration of 100 microseconds for 20 minutes. The electrode will be placed so that two electrodes from one channel are placed on the paravertebral muscles of the neck and two electrodes from the other channel are placed on the upper trapezius muscles. The hot pack will also be used at the same time as using TENS on the electrodes. In addition, Continuous ultrasound waves with a frequency of 1 MHz and an intensity of 1 w / cm2 will be used for 5 minutes on the posterior muscles of the upper vertebrae. It also teaches the patient exercise therapy using active exercises.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Dr. Mohammad Reza Najafi
Street address
Esfahan - Shahid Keshvari Highway - Safa Boulevard - Alzahra Medical Center
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2

Recruitment center
Name of recruitment center
kashani hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

Street address
Hezar Jarib Street, Isfahan University of Medical Sciences, Staff Building No. 4 - Vice chancellor for research

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research@mui.ac.ir

Web page address
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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Ehsan Ghasemi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Position
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

We are not able to publish data ethically and misuse information.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The study protocol and consent form are included in the proposal.Clinical results will be published after the end of study.

When the data will become available and for how long

The study protocol and the name consent form are already available. Clinical results will be published in the summer of 1400.

To whom data/document is available

Researchers working in scientific institutes and patients.

Under which criteria data/document could be used

To increase information.

From where data/document is obtainable

See Dr. Ehsan Ghasemi.

What processes are involved for a request to access data/document

They can send their requests via email.

Comments