Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation the effect of exercise therapy and perineural electrical dry needling on the severity, frequency and disability of patients with cervicogenic headache: a randomized clinical trial.

Protocol summary

Study aim

Determination the effect of exercise therapy and perineural electrical dry needling on the severity, frequency and disability of patients with cervicogenic headache

Design

Clinical trial with control group, double-blind, randomized on 26 patients. The rand function of Excel software was used for randomization.

Settings and conduct

After obtaining informed consent, all participants will be randomly assigned to two intervention and control groups if they meet the inclusion criteria. This study is conducted in the sports medicine department of Sinai Hospital. The patients in both the control and intervention groups are not aware of the type of intervention that will be performed for them, and all the study steps for these two groups are conducted in separate sessions. the evaluator is also unaware of the intervention on the two groups.

Participants/Inclusion and exclusion criteria

The participants in this research include 26 patients with cervicogenic headache who, according to laboratory, clinical or imaging evidence, have evidence of a neck disorder causing headache, and if the patient is unable to complete the therapy and acupuncture exercise sessions or suffers an injury during the study or any disorder, will be removed from the study.

Intervention groups

The intended intervention consists of 8 sessions of 20-30 minutes of perineural electrical dry needling with a frequency of 50 Hz and home exercises during 6 weeks. Exercises are done 5 days a week, 3 times a day and at home. In the control group, exercises are prescribed.

Main outcome variables

Headache intensity; drugs used; duration of each headache attack; location of headache; Frequency and changes in headache characteristics are assessed. Also, the degree of disability; The headache impact test and the global rating of change score after acupuncture sessions and sports exercises.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240315061292N1**
Registration date: **2024-05-05, 1403/02/16**
Registration timing: **prospective**

Last update: **2024-05-05, 1403/02/16**
Update count: **0**

Registration date

2024-05-05, 1403/02/16

Registrant information

Name

Marzieh Mahmoudi Zarandi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-21, 1403/04/01

Expected recruitment end date

2025-06-22, 1404/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of exercise therapy and perineural electrical dry needling on the severity, frequency and disability of patients with cervicogenic headache: a randomized clinical trial.

Public title

Evaluation the effect of exercise therapy and perineural electrical dry needling on the severity, frequency and disability of patients with cervicogenic headache: a randomized clinical trial.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The presence of laboratory, clinical and/or imaging evidence of a neck disorder, known to be able to cause headache. A headache that has at least 2 of the following 4 criteria: A) Headache in the temporal region that is related to the presence of neck disorders. B) Headache that improves in parallel with the improvement of the neck disorder. C) Cervical range of motion Is reduced and headache made worse by provocative manoeuvres. D) Headache is abolished following cervical diagnostic anaesthetic blockade. There is no other diagnosis for headache. Definitive diagnosis of cervicogenic headache by a neurologist based on HIS criteria. Absence of orthopedic disorders and diseases such as cervical discopathy that prevent exercises. The patient has not participated in a regular exercise program or physical therapy during the last 4 weeks. The patient has not been treated with corticosteroids (injection or oral) in the last 2 weeks.

Exclusion criteria:

The patient suffers an injury or any disorder during the study that prevents him or her from performing and continuing exercises and acupuncture. The patient is unable to complete acupuncture sessions. The patient's unwillingness to complete the exercise program and acupuncture sessions. Follow-up through the logbook has missed 30% of the exercises. A history of bleeding disorders or the use of anticoagulant drugs Suffering from psychiatric disorders

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

After meeting the inclusion criteria for entering the study, the patients will be randomly placed in one of two groups A or B using the block randomization method using a sealed envelope. Consecutive but equal times, they enter the intervention and control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patients in both the control and intervention groups are not aware of the type of intervention that will be performed for them, and all study steps for these two groups are conducted in separate sessions. Also, the evaluator is not aware of the intervention on the two groups.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Sina Hospital - Tehran University of Medical Sciences

Street address

Sports Medicine Department, Sina Hospital, Hassan Abad Square, Imam Khomeini Street

City

Tehran

Province

Tehran

Postal code

1136746911

Approval date

2023-05-06, 1402/02/16

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1402.018

Health conditions studied

1

Description of health condition studied

Cervicogenic headache

ICD-10 code

G44.8

ICD-10 code description

Headache associated with sexual activity

Primary outcomes

1

Description
Pain intensity based on the Numerical Pain Rating Scale (NPRS)
Timepoint
At the beginning of the study and after 6 weeks
Method of measurement
The Numerical Pain Rating Scale (NPRS)

Secondary outcomes

1

Description
Patient's disability
Timepoint
At the beginning of the study and after 6 weeks
Method of measurement
The Neck Disability Index (NDI)

2

Description
Pain intensity
Timepoint
At the beginning of the study and after 6 weeks
Method of measurement
Headache Impact Test (HIT-6): This test consists of 6 questions and shows the impact of headache on the patient's life. For each question, a score between 6 and 13 is considered.

3

Description
The Global Rating of Change Score (GROC)
Timepoint
At the beginning of the study and after 6 weeks
Method of measurement
This questionnaire measures the overall changes in recovery and can include values from negative 7 to positive 7.

Intervention groups

1

Description
Intervention group: The intended intervention consists of 8 sessions of 20-30 minutes of dry needling with perineural electrical stimulation with a frequency of 50 Hz and home exercises during 6 weeks. These exercises in both groups include neck and periscapular exercises. The exercises are performed 5 days a week, 3 times a day and at home. The patients are instructed to stop the exercises and inform the researcher if the symptoms worsen and the pain worsens more than 3.10 NPRS. In addition to the exercises, the intervention group is treated with dry needling with perineural electrical stimulation. Acupuncture is performed on the trigger points that are performed by the doctor during the initial examination. These points can be located in the occipital, paraspinal, periscapular and trapezius muscle areas. Acupuncture sessions are done 2 days a week with an at least one day between two sessions. After each session, the patient is asked about the regular exercise, and if necessary, retraining and correction of movements is done. All patients are trained about sports exercises in person, and in order to prevent forgetting and perform them correctly, exercises are presented to patients in the form of a logbook with pictures and explanations.
Category
Treatment - Other

2

Description
Control group: In the control group, exercises are prescribed. These exercises are performed at least 5 days a week, 3 times a day and at home. Patients in the control group are regularly followed up by phone once every two weeks, in order to motivate and check the performance of exercises. Explanations and pictures related to sports exercises are attached in the form of a training logbook.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Marzieh Mahmoudi Zarandi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Research and Technology Vice-Chancellor, 6th floor, Central Organization of the University, corner of Quds St., Keshavarz Blvd

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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
Tehran 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
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Position
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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
Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

The access period starts 3 months after the results are published.

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions or people who are also engaged in industry and can apply to receive them.

Under which criteria data/document could be used

The use of data for other scientific researches is permitted by mentioning the source.

From where data/document is obtainable

m.m.z.of7sky@gmail.com

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

At first, the researcher sends an e-mail stating the request to the mentioned e-mail address, and then after a maximum of 1 month, the investigation is done and the documents are sent to the e-mail address of the researcher.

Comments