

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of dry needling technique on clinical parameters of patients with migraine headache: A Randomized Clinical Controlled Trial

Protocol summary

Study aim

The effects of dry needling technique on clinical parameters of patients with migraine headache.

Design

A randomized, single blinded, controlled clinical trial with parallel group design of 40 patients with migraine headache (20 subjects per each group).

Settings and conduct

The study will be conducted in rehabilitation school of the Tabriz University of Medical Sciences. The participants in the intervention group will receive dry needling of the upper trapezius muscle trigger points during 3 sessions, while using routine migraine medication. The control group will only receive routine medication. The study will be single blind (only evaluator).

Participants/Inclusion and exclusion criteria

Inclusion criteria: The diagnosis of migraine headache, having headache more than 3 months, Negative Flex - Rot test, presence of active trigger points in the upper trapezius muscle. Exclusion criteria: A history of neck trauma, Cervical radiculopathy, cervical or shoulder surgery, history of trigger point injection, needle phobia, pregnancy, vascular disease.

Intervention groups

The participants in the intervention group will be treated with dry needling in the upper trapezius muscle during 3 sessions plus routine medications. The interval between sessions is one week. For dry needling, the needle enters the active trigger point of the upper trapezius muscle and local twitch response is observed. Then, the needle pulls out, but does not leave the skin and enters the trigger point again. This is repeated until no local twitch response is detected with 10 manipulations. Participants in the control group will receive only medication.

Main outcome variables

Headache intensity (as a primary outcome), Frequency and duration of headache, Drug consumption, Pain pressure threshold and pain intensity of the upper

trapezius muscle trigger points.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200215046499N2**

Registration date: **2021-12-06, 1400/09/15**

Registration timing: **prospective**

Last update: **2021-12-06, 1400/09/15**

Update count: **0**

Registration date

2021-12-06, 1400/09/15

Registrant information

Name

Hakimeh Adigozali

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of dry needling technique on clinical parameters of patients with migraine headache: A Randomized Clinical Controlled Trial

Public title

The effects of dry needling on clinical parameters of patients with migraine headache: A Randomized Clinical Controlled Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The diagnosis of migraine headache based on the International Headache Society (IHS) criteria: A. At least five attacks fulfilling criteria. B. Headache attacks lasting 4-72 hours. C. Headache has at least two of the following four characteristics: 1. Moderate or severe pain intensity 2. Pulsating quality 3. Aggravation by routine physical activity 4. Unilateral location D. During headache at least one of the following: 1. Nausea and/or vomiting 2. Photophobia and phonophobia. Confirmation of the presence of active trigger point in the upper trapezius muscle, according to following criteria: Taut band in the upper trapezius muscle, presence of a hypersensitive nodule, and familiar referral pain. Having migraine headache for more than 3 months. Negative Flex -Rot Test

Exclusion criteria:

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with a sealed envelope: Two envelopes are prepared with the first and second group titles. Each participant randomly selects one envelope and the envelope number is recorded for the participant. The envelopes are then merged and the next participant selects another envelope from the two envelopes as the previous procedure to complete the randomization process in both groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluator is blind to the type of intervention in each group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Faculty of Rehabilitation Sciences, Tabriz University of medical sciences, 29 Bahman Blvd, Tabriz, Iran.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2021-08-02, 1400/05/11

Ethics committee reference number

IR.TBZMED.REC.1400.430

Health conditions studied

1

Description of health condition studied

Migraine headache

ICD-10 code

G43

ICD-10 code description

Migraine

Primary outcomes

1

Description

Headache intensity

Timepoint

Pre intervention, immediately post treatment, 7 and 14 days after the first session, 30 days after the last session.

Method of measurement

Daily Headache Diary form

Secondary outcomes

1

Description

Headache frequency

Timepoint

Pre intervention, immediately post treatment, 7 and 14 days after the first session, 30 days after the last session.

Method of measurement

Daily headache diary form

2**Description**

Headache duration

Timepoint

Pre intervention, immediately post treatment, 7 and 14 days after the first session,30 days after the last session.

Method of measurement

Daily headache diary form

3**Description**

Drug consumption

Timepoint

Pre intervention, immediately post treatment, 7 and 14 days after the first session,30 days after the last session.

Method of measurement

Daily headache diary form

4**Description**

Pressure pain threshold of upper trapezius muscle trigger points

Timepoint

Pre intervention, immediately post treatment, 7 and 14 days after the first session.

Method of measurement

A digital algometer

5**Description**

Pain intensity of upper trapezius trigger points

Timepoint

Pre intervention, immediately post treatment, 7 and 14 days after the first session.

Method of measurement

Visual Analogue Scale

Intervention groups**1****Description**

The intervention group: The participants in the intervention group will be treated with routine medications plus dry needling in the upper trapezius muscle during 3 sessions. The interval between sessions sets at one week. Sterilized stainless steel needles (50 ×0.25 mm (Dong - Bang, Korea) will be used for dry needling.

Category

Rehabilitation

2**Description**

Control group: Participants in this group will receive

routine migraine medications.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person

Hakimeh Adigozali

Street address

Imam Reza General Hospital , Across from Central Building of Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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Central Building, Tabriz University of Medical Sciences, University Street, Tabriz.

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Hakimeh Adigozali

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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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