Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

Phone
+98 41 3337 5359

Email address
adigozalih@tbzmed.ac.ir

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 intensity2. Pulsating quality3. 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.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3382 8385
Email
Adigozalih@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parviz Shahabi
Street address
Central Building, Tabriz University of Medical Sciences, University Street, Tabriz.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3337 6923
Email
parvizshahabi@gmail.com
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

Street address

Faculty of rehabilitation sciences, Tabriz university of medical sciences, 29 Bahman Blvd.

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone

+98 41 3337 5359

Email

Adigozalih@tbzmed.ac.ir

Person responsible for scientific 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

Street address

Faculty of rehabilitation sciences, Tabriz university of medical sciences, 29 Bahman Blvd.

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone

+98 41 3337 5359

Email

Adigozalih@tbzmed.ac.ir

Person responsible for updating data

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

Street address

Faculty of rehabilitation sciences, Tabriz University of Medical Sciences, 29 Bahman Blvd.

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone

+98 41 3337 5359

Email

Adigozalih@tbzmed.ac.ir

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