

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparison of effect of dry needling, physiotherapy, and sham dry needling in cervicogenic headache- A randomized controlled clinical trial

Protocol summary

Study aim

Comparison of effect of dry needling, physiotherapy, and sham dry needling in cervicogenic headache

Design

A triple blind randomized clinical trial consisting of three routine physiotherapy groups and a routine physiotherapy with dry needles and a routine physiotherapy with a placebo needle.

Settings and conduct

Patients in the routine physical therapy group for fifteen sessions, three times a week, will undergo physiotherapy including electrical stimulation, surface heat, neck ultrasound and neck stabilization exercises. In dry needle group, in addition to the above items, dry needle will be performed according to the Dommerholt method for 4 sessions and the second, fifth, eighth and twelfth sessions will be performed at the active trigger points of the upper trapezius muscles, cervical erector spine muscles and sternocleidomastoid. In the placebo group, the needle is very superficial and at a point away from active trigger points during 4 sessions in the muscles, so that we can differentiate the effects of placebo needle dry from its actual effects. The assessments will be done before the treatment immediately after treatment, one month later, three and six months later.

Participants/Inclusion and exclusion criteria

Unilateral headache Starting in the neck Pain aggravated by neck movement Restricted cervical range of motion Joint tenderness in the joints of the upper cervical spine Active trigger point in neck muscles

Intervention groups

The cervicogenic headache are randomly divided into three groups. The first group routine physiotherapy, the second group routine physiotherapy and dry needle, the third group routine physiotherapy and placebo needle

Main outcome variables

The severity and frequency of headaches, Neck range of motion, pressure Pain threshold and tenderness at the trigger point of the muscles, Function of deep neck flexor

muscles, neck proprioception

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180721040539N1**

Registration date: **2018-09-24, 1397/07/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-24, 1397/07/02**

Update count: **0**

Registration date

2018-09-24, 1397/07/02

Registrant information

Name

Roghayeh Mousavi-khatir

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of effect of dry needling, physiotherapy, and sham dry needling in cervicogenic headache- A randomized controlled clinical trial

Public title
The effect of dry needling in cervicogenic headache- A randomized controlled clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Unilateral pain Starting in the neck and radiating to the frontotemporal region Pain aggravated by neck movement Restricted cervical range of motion Joint tenderness in at least one of the joints of the upper cervical spine (C1-C3) Headache frequency of at least 1 per week over a period greater than 3 months Active trigger point in the suboccipital and upper trapezius and sternocleidomastoid muscles
Exclusion criteria:
Cervical radiculopathy A history of spinal or shoulder trauma or spinal surgery History of physical therapy intervention in the neck and shoulder region within the previous 6 months Diagnosed primary headache Needle phobia

Age
From **19 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
At first, a physiotherapist with ten years of experience perform patient's physical examination. If they meet the conditions for entry into the study, and don't have exclusion criteria, a randomization into three groups (control and DN group, sham DN group) was performed by packed envelopes via blind independent researcher to aim of allocation concealment.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In sham dry needling group, the patient will not be aware of the fact that he/she does not receive the actual dry needling. The assessor and therapist will two different individuals and assessor blind to intervention. Also , statistical analysis will be done by a person who is blind to grouping

Placebo
Used

Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

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University of Medical Sciences , Ganjafrooz Street , Babol , Mazandaran ,Iran

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Approval date

2018-06-10, 1397/03/20

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.071

Health conditions studied

1

Description of health condition studied

cervicogenic headache patients

ICD-10 code

G44.0

ICD-10 code description

Other headache syndromes

Primary outcomes

1

Description

intensity of the headache

Timepoint

Before treatment, immediately after treatment, one , three and six month later

Method of measurement

questionnaire

2

Description

headache frequency

Timepoint

Before treatment, immediately after treatment, one , three and six month later

Method of measurement

questionnaire

3

Description

Neck range of motion

Timepoint

Before treatment, immediately after treatment, one , three and six month later

Method of measurement

Goniometry

4

Description

Function of deep neck flexor muscles

Timepoint

Before treatment, immediately after treatment, one , three and six month later

Method of measurement

pressure biofeedback

5

Description

Pressure pain threshold and tenderness at the trigger point of the muscles

Timepoint

Before treatment, immediately after treatment, one , three and six month later

Method of measurement

Algometer

6

Description

Neck proprioception

Timepoint

Before treatment, immediately after treatment, one , three and six month later

Method of measurement

laser pointer and software

Secondary outcomes

1

Description

Quality of life

Timepoint

Before treatment, Immediately after treatment, One month later, Three months and Six month later

Method of measurement

Quality of life questionnaire

2

Description

Functional rating index

Timepoint

Before treatment, Immediately after treatment, One month later, Three months and Six month later

Method of measurement

Functional rating index-questionnaire

Intervention groups

1

Description

Intervention group 1: Routine physiotherapy and dry needle

Category

Rehabilitation

2

Description

Intervention group2: Routine physiotherapy and placebo needle

Category

Rehabilitation

3

Description

Intervention group 3: Routine physiotherapy

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Educational and Therapeutic Center

Full name of responsible person

Roghayeh Mousavi-Khatir

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Sponsors / Funding sources

1

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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

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Khodabakhsh Javanshir

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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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