Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Country
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 sternoclidomastoid 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

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

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47176-47745

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
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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
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Associate professor
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Person responsible for updating data

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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