

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effectiveness of one session dry needling of Sternocleidomastoid on pain and disability in patient with cervicogenic headache

Protocol summary

Study aim

investigating the effect of dry needling of sternocleidomastoid on pain and disability in patient with cervicogenic headache

Design

Quasi-experimental Study, Before and After clinical trial

Settings and conduct

Twenty patients with a clinical diagnosis of Cervicogenic headache and active trigger points in the sternocleidomastoid muscle are screen for eligibility criteria. Then the patient is asked to write headache frequency and headache duration (by hours) and headache intensity (by visual analogue scale) within 2 weeks and fill Persian version of headache disability questionnaire, after 2 weeks they receive trigger point dry needling of Sternocleidomastoid muscle, and they are requested to write headache frequency and headache duration and headache intensity within 2 weeks after intervention and fill Persian version of headache disability questionnaire again.

Participants/Inclusion and exclusion criteria

inclusion criteria: patient with unilateral headache that headache frequency of at least 1 per week over a period greater than 3 months. exclusion criteria: dry needling contraindication, history of diagnosed primary headache

Intervention groups

one session dry needling of sternocleidomastoid muscle

Main outcome variables

pain and disability in patient with cervicogenic headache

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181109041599N1**

Registration date: **2019-05-04, 1398/02/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-04, 1398/02/14**

Update count: **0**

Registration date

2019-05-04, 1398/02/14

Registrant information

Name

Zahra Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3261 0840

Email address

zahra.mohammadi_73@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of one session dry needling of Sternocleidomastoid on pain and disability in patient with cervicogenic headache

Public title

Effect of dry needling in treatment of cervicogenic headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

unilateral pain that radiating to the frontotemporal region pain aggravated by neck movement and/or sustained awkward head positions moderate to severe non throbbing pain presence of active trigger points in the sternocleidomastoid muscle Having reading and writing skills headache frequency of at least 1 per week over a period greater than 3 months

Exclusion criteria:

cervical radiculopathy a history of neck trauma; trigger point therapy or trigger point dry needling in the neck within the previous 6 months subjects > 65 y due to vascular defects evidence of cognitive deficits dry needling contraindication : needle phobia, pregnancy, ... previously had surgery in the neck or shoulder area a history of diagnosed primary headache the presence of any tumor in the region systemic disease: diabetes, anemia and ...

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahanm university of medical sciences

Street address

departement of rehabilitationT, Isfahan University Of Medical sciences, University Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-01-23, 1397/11/03

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.374

Health conditions studied**1****Description of health condition studied**

cervicogenic headache

ICD-10 code

G44

ICD-10 code description

Other headache syndromes

Primary outcomes**1****Description**

headache intensity

Timepoint

2 weeks before and 2 weeks after intervention

Method of measurement

visual analogue scale

Secondary outcomes**1****Description**

headache frequency

Timepoint

2 weeks before and 2 weeks after intervention

Method of measurement

days with headache

2**Description**

headache duration

Timepoint

2 weeks before and 2 weeks after intervention

Method of measurement

hours with headache

3**Description**

headache disability index

Timepoint

2 weeks before and 2 weeks after intervention

Method of measurement

Persian version of headache disability

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

Intervention group: one session trigger point dry

needling of Sternocleidomastoid muscle which is performed 10 times in the muscle.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation department

Full name of responsible person

Zahra Mohammadi

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rehabilitation department, Isfahan university of medical science, university Blvd, Isfahan, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooye javanmard

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Mohammadi

Position

student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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rehabilitation department, Isfahan university of medical science, university Blvd, Isfahan, Isfahan

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

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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

Individual Participant Data: all collected deidentified IPD

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

using for Supplementary study

From where data/document is obtainable

e-mail address : Zahra.mohammadi_73@yahoo.com

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

name, address, position, title of study and protocol of
study

Comments