

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

**Street address**

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

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81174673461

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+98 31 3792 5000

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tavanbakhshi@rehab.mui.ac.ir

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

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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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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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student

**Latest degree**

Master

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## Person responsible for updating data

### Contact

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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**