

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### A Sonographic Comparison of Effect of Dry Needling and Ischemic Compression on Active Trigger Point of the Sternocleidomastoid Muscle associated with Cervicogenic Headache

#### Protocol summary

##### Study aim

The aim of this study was to compare the effects of dry needling and ischemic compression on the clinical symptoms of cervicogenic headache originating from active trigger point in the sternocleidomastoid muscle and the biomechanical properties of, using ultrasonography imaging.

##### Design

The randomized clinical trial, with the aim of treatment, parallel group

##### Settings and conduct

After signing the informed consent, a form was given to the subjects to record headache parameters over the following two weeks. Subjects were assessed and then randomly distributed in three groups: control, ischemic compression, or dry needling. After intervention sessions, subjects were evaluated again. All study process was done at Tarbiat Modares University.

##### Participants/Inclusion and exclusion criteria

Subjects were eligible with cervicogenic headache from trigger point in the sternocleidomastoid muscle. They were excluded if they had other types of headaches, had active trigger point in the other muscles of the neck and face, needle phobia, rheumatologic diseases, neck or shoulder surgery, or had any contraindications for interventions.

##### Intervention groups

Subjects were supine and the trigger point was compressed between the physiotherapist's thumb and index finger in the ischemic compression group. In the dry needling group, the trigger point was grasped between the physiotherapist's fingers and a needle was repeatedly inserted in the anterior-posterior direction.

##### Main outcome variables

Headache intensity, Headache duration, Headache frequency

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160621028567N1**

Registration date: **2019-02-10, 1397/11/21**

Registration timing: **retrospective**

Last update: **2019-02-10, 1397/11/21**

Update count: **0**

##### Registration date

2019-02-10, 1397/11/21

##### Registrant information

##### Name

**Name of organization / entity**

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8288 3559

##### Email address

m.jafarii@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-23, 1397/06/01

##### Expected recruitment end date

2019-03-21, 1398/01/01

##### Actual recruitment start date

2018-09-01, 1397/06/10

##### Actual recruitment end date

2018-12-30, 1397/10/09

##### Trial completion date

2018-12-31, 1397/10/10

**Scientific title**

A Sonographic Comparison of Effect of Dry Needling and Ischemic Compression on Active Trigger Point of the Sternocleidomastoid Muscle associated with Cervicogenic Headache

**Public title**

The comparison of effect of dry needling and ischemic compression for cervicogenic headache

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Cervicogenic headache Active trigger point in the sternocleidomastoid muscle inducing headache

**Exclusion criteria:**

Other types of headache Active trigger points in the other muscles of neck and face Needle phobia Rheumatological diseases Neck and shoulder surgery Any contraindications for interventions

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **30**

Actual sample size reached: **29**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

By simple randomization method, subjects were assigned to ischemic compression group(n=9), dry needling group (n=10), or control group (n=10). The sealed envelope was used for randomized allocation of subjects to the groups. In this way, subjects selected one of 29 similar sealed envelopes. Inside the envelopes were the name of one of the three groups that led to the assignment of the subjects to that group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Committee of Ethics in Biomedical Research, Tarbiat

Modares University

**Street address**

Jala Ale Ahmad, Nasr

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713116

**Approval date**

2015-12-22, 1394/10/01

**Ethics committee reference number**

IR.TMU.REC.1394.163

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

Cervicogenic headache

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Headache intensity

**Timepoint**

At the beginning of the study, two weeks after end of interventions

**Method of measurement**

Designed form for recording the clinical characteristics of headache

**2****Description**

Headache duration

**Timepoint**

At the beginning of the study, two weeks after end of interventions

**Method of measurement**

Designed form for recording the clinical characteristics of headache

**3****Description**

Headache frequency

**Timepoint**

At the beginning of the study, two weeks after end of interventions

**Method of measurement**

Designed form for recording the clinical characteristics of headache

**Secondary outcomes**

### 1

**Description**

Elastic modulus

**Timepoint**

At the beginning of the study, two weeks after end of intervention

**Method of measurement**

Ultrasound

### 2

**Description**

Trigger point area

**Timepoint**

At the beginning of the study, two weeks after end of intervention

**Method of measurement**

Ultrasound

### 3

**Description**

Pressure pain threshold

**Timepoint**

At the beginning of the study, two weeks after end of intervention

**Method of measurement**

Force gauge

## Intervention groups

### 1

**Description**

Intervention group: ischemic compression. Subjects in the ischemic compression group were asked to lie in a supine position with their heads in contralateral rotation, the trigger point taut band was grasped between the clinician's thumb and index finger and for 30-60 seconds maximal tolerable pressure was applied. This process was repeated three times with 30-second intervals. If the headache pattern was reproduced or the pain disappeared, ischemic compression was discontinued. The intervention was repeated 4 sessions within 8 days with one-day intervals between each treatment session.

**Category**

Rehabilitation

### 2

**Description**

Intervention group: dry needling. For the dry needling group, subjects were supine with neutral head, the trigger point was grasped between the clinician's thumb, index, and middle fingers and a 0.25×40mm needle (DongBang Acuprime) was repeatedly inserted in the anterior-posterior direction as long as local twitch responses were extinct. The intervention was repeated 4 sessions within 8 days with one-day intervals between each treatment session.

**Category**

Rehabilitation

### 3

**Description**

Control group: no intervention. Subjects in the control group did not receive any treatments.

**Category**

N/A

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Dr Togha Headache Clinic

**Full name of responsible person**

Mansoureh Togha

**Street address**

Iranema Physician Building, 24th Ave, Ghaem Magham Ave, Haft-e Tir Square

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toghae@sina.tums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Mohammad Taghi Ahmadi

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mahmadi@modares.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tarbiat Modares University

**Proportion provided by this source**

50

**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**  
Tarbiat Modares University  
**Full name of responsible person**  
Farid Bahrpeyma  
**Position**  
Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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m.jafarii@modares.ac.ir

## 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

part of data

### When the data will become available and for how long

6 months after publication

### To whom data/document is available

Researchers

### Under which criteria data/document could be used

for treatment and research goals

### From where data/document is obtainable

Dr Farid Bahrpeyma bahrpeyf@modares.ac.ir

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

Confirmation of advisor professor

### Comments