

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The Investigation of the Effects of Deep Dry Needling into Trigger Points of Temporalis, Sternocleidomastoid and Upper Trapezius on Females with Episodic Tension Type Headache

#### Protocol summary

##### Study aim

The aim of this study is to investigate the effects of deep dry needling into trigger points of Temporalis, Sternocleidomastoid and upper Trapezius muscles in women with episodic tension type headache.

##### Design

A blocking Randomized, Single-blinded, controlled clinical trial with a parallel group design including 24 patients

##### Settings and conduct

Patients with headache in the Headache Center of Sina Hospital will be selected and signing the informed consent, will be instructed to record the headache parameters over 4 weeks. They will be assessed and will be randomly assigned to control and intervention groups. The assessment will be done before treatment and 1 month after treatment. All stages will be carried out at the School of Rehabilitation Sciences, Iran University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : Having episodic tension type headache (ETTH) based on international classification of headache (ICHD-3) ; Having at least one active trigger point in one of the given muscles : Temporalis (Left or Right), upper Trapezius (Left or Right), Sternocleidomastoid (Left or Right). Exclusion criteria : Having other primary or secondary headaches; History of neck injury; Acute depression ; Cervical radiculopathy ; History of surgery in neck or shoulder ; Pregnant women.

##### Intervention groups

Intervention group: The patients will receive one session of deep dry needling at one trigger point (active or latent) in the temporalis, sternocleidomastoid, and upper trapezius muscles in both sides. Then, they will receive passive stretching of the aforementioned muscles in both sides. Control group: The patients will receive only one session of passive stretching similar to the intervention

group.

##### Main outcome variables

Headache intensity ; Headache frequency

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200129046302N1**

Registration date: **2020-02-26, 1398/12/07**

Registration timing: **retrospective**

Last update: **2020-02-26, 1398/12/07**

Update count: **0**

##### Registration date

2020-02-26, 1398/12/07

##### Registrant information

##### Name

Soheil Mansour Sohani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 8051

##### Email address

mansorsohani.s@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-06, 1397/12/15

##### Expected recruitment end date

2019-09-20, 1398/06/29

##### Actual recruitment start date

2019-03-15, 1397/12/24

**Actual recruitment end date**

2019-10-21, 1398/07/29

**Trial completion date**

2019-10-21, 1398/07/29

**Scientific title**

The Investigation of the Effects of Deep Dry Needling into Trigger Points of Temporalis, Sternocleidomastoid and Upper Trapezius on Females with Episodic Tension Type Headache

**Public title**

The Investigation of the Effects of Deep Dry Needling in Females with Episodic Tension Type Headache

**Purpose**

Treatment

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

Having a diagnosis of Episodic tension type headache (ETTH) based on the International Classification of Headache Disorders(ICHHD-3) Having at least one active trigger point in one of the given muscles : Temporalis(Left or Right), upper Trapezius(Left or Right) , Sternocleidomastoid (Left or Right)

**Exclusion criteria:**

Having primary or secondary headaches History of neck injury Acute depression History of surgery in neck and shoulder Cervical radiculopathy History of dry needling treatment in the neck or head for the past six months Pregnant women

**Age**

From **18 years** old to **50 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **26**

Actual sample size reached: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be randomly assigned to the intervention or control groups. The random allocation method of these two groups will be block randomization. Block size will comprise 6 persons (overall there will be 4 blocks). Random allocation software will be used to determine the sequence of patient's allocation to each group.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Pre-treatment,post-treatment assessments will be performed by the physiotherapist who is supposed to be blinded to the allocation concealment.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

- Ethics committee of Iran university of medical sciences

**Street address**

Iran university of medical sciences, next to Milad tower, Hemmat highway

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۳۹۶۱۴۵۳۵

**Approval date**

2019-02-23, 1397/12/04

**Ethics committee reference number**

IR.IUMS.REC.1398.048

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

Episodic tension type headache

**ICD-10 code**

G44.21

**ICD-10 code description**

Episodic tension-type headache

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

Headache intensity

**Timepoint**

Headache intensity assessment at the baseline(4 weeks before intervention) and 4 weeks after intervention

**Method of measurement**

Visual analogue scale

**2****Description**

Headache frequency

**Timepoint**

Headache frequency assessment at the baseline(4 weeks before intervention) and 4 weeks after intervention

**Method of measurement**

The number of days with headache within 4 weeks

**Secondary outcomes**

## 1

### **Description**

Neck range of motion

### **Timepoint**

At the beginning of the intervention , immediately , 2 and 4 weeks after intervention

### **Method of measurement**

Goniometer

## 2

### **Description**

Mouth opening range of motion

### **Timepoint**

At the beginning of the intervention , immediately , 2 and 4 weeks after intervention

### **Method of measurement**

Ruler

## 3

### **Description**

Trigger points pain pressure threshold

### **Timepoint**

At the beginning of the intervention , immediately , 2 and 4 weeks after intervention

### **Method of measurement**

Algometer

## 4

### **Description**

Quality of life

### **Timepoint**

before intervention and 4weeks after intervention

### **Method of measurement**

SF-36 Quality of life Questionnaire

## 5

### **Description**

Sleep quality

### **Timepoint**

before intervention and 4weeks after intervention

### **Method of measurement**

Pittsburgh sleep quality questionnaire

## **Intervention groups**

### 1

#### **Description**

Intervention group:Single session treatment with deep dry needling(Dongbang model, South Korea, 50\*0/3 mm)in the trigger points of the Temporalis, Sternocleidomastoid and upper Trapezius muscles in both sides(after obtaining one local twitch response ,the needle will be inserted 8 times with fast in fast out technique )following with passive stretching( 4 seconds of stretching and 8 seconds of rest , this cycle will be repeated 3 times for each muscle).

#### **Category**

Rehabilitation

### 2

#### **Description**

Control group: Single session of passive stretching in the Temporalis, Sternocleidomastoid and upper Trapezius muscles in both sides (4 seconds of stretching and 8 seconds of rest , this cycle will be repeated 3 times for each muscle).

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Headache center of Sina Hospital

##### **Full name of responsible person**

Dr.Mansoure Togha

##### **Street address**

Imam Khomeini St., Hassan Abad Sq., Sina Hospital

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

113746911

##### **Phone**

+98 21 6634 8500

##### **Email**

hosp\_sina@sina.tums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Iran University of Medical Sciences

##### **Full name of responsible person**

Dr. Seyyed Abbas Motevalian

##### **Street address**

Iran university of medical sciences,Milad tower,Hemmat highway

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1449614535

##### **Phone**

+98 21 8670 2503

##### **Email**

motevalian.a@iums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**  
Iran 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**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Faezeh Abaschian  
**Position**  
Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Physiotherapy  
**Street address**  
No18.Shahid Ahmadian Ave,Torkamenstan  
Str.Motahari Str  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
23478-87688  
**Phone**  
+98 21 8844 6048  
**Email**  
faezeh\_abaschian@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Soheil Mansour Sohani  
**Position**  
Assiatant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Physiotherapy  
**Street address**  
School of Rehabilitation Sciences, Iran University of  
Medical Sciences, Maddadkaran St., Shahid Nazari St.,  
Mother Square, Mirdamad Blvd  
**City**  
Tehran  
**Province**

Tehran  
**Postal code**  
۱۳۴۸۷ - ۱۵۴۵۹  
**Phone**  
+98 21 2222 2059  
**Email**  
mansorsohani.s@iums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Soheil Mansour Sohani  
**Position**  
Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Physiotherapy  
**Street address**  
School of Rehabilitation Sciences, Iran University of  
Medical Sciences, Maddadkaran St., Shahid Nazari St.,  
Mother Square, Mirdamad Blvd  
**City**  
Tehran  
**Province**  
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**Postal code**  
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**Phone**  
+98 21 2222 2059  
**Email**  
mansorsohani.s@iums.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

Not applicable

### 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

all data will be shared after unidentified persons.

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

accessibility will be 6 months after printing the result.

### To whom data/document is available

all researchers and scientists, working in academic and scientific institutions, can access to data.

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

Using of data is only possible by mentioning the name

and organizational affiliation of the correspond and co-author of the project and the published article.

**From where data/document is obtainable**

faezeh\_abaschian@yahoo.com

**What processes are involved for a request to access**

**data/document**

If data is used in scientific and therapeutic activities, information will be provided within 2 weeks.

**Comments**