

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effects of treating myofascial trigger points of neck using the techniques of dry needling and soft tissue release on the clinical feature of patients with migraine headache

#### Protocol summary

##### Study aim

The effect of trigger point therapy with dry needling and soft tissue release Techniques on clinical indexes of migraine headache patients

##### Design

Sixty migraine patients who are referred to the Neurology Clinic of Shiraz Medical Sciences Hospital are selected. The participants are randomly divided into three groups of control, DN and STR.

##### Settings and conduct

Migraine patients are evaluated for the presence of TRPs in UT, suboccipital, and SCM muscles. In the presence of TRPs in these muscles, subjects are assigned to three groups of control, DN and STR according to block randomization. The two-blind study will be conducted in such a way that people are assigned to groups and patients are evaluated by people who are unaware. Treatment is provided by a specialist physiotherapist and evaluated by a collaborator.

##### Participants/Inclusion and exclusion criteria

Inclusion: 1- Selection of patients according to International Headache Society criteria by neurologist . 2 - Active trigger points in the upper trapezius, sternocleidomastoid and suboccipital muscles. Exclusion: Cervical disc herniation, unusual migraine, pregnant subjects, and patients have contraindication for needling.

##### Intervention groups

Dry needling (DN): It is used on the trigger point (TRP) in the UT, SCM and suboccipital muscles. The needle is applied for three sessions. Soft Tissue Release (STR): It is included SCM muscle TRP therapy, suboccipital muscle inhibition, UT muscle TRP therapy, long axis longitudinal stretch, bilateral-lateral stretch. Patients receive each technique with repeated 5 times for 6 days. Control group: After the trigger points are determined, the therapist applied soft and superficial massage on the involved muscles.

##### Main outcome variables

1. Pain intensity 2. Pressure pain threshold 3. Muscle thickness 4. Disability Index 5. Cervical range of motions measurement 6-Headache parameters

#### General information

##### Reason for update

Since our study is prospective and unfortunately the starting date of the sample entry was incorrectly 2017 instead of 2018, we made the corrections.

##### Acronym

DNSTR

##### IRCT registration information

IRCT registration number: **IRCT20171219037956N1**

Registration date: **2018-02-11, 1396/11/22**

Registration timing: **prospective**

Last update: **2020-01-02, 1398/10/12**

Update count: **1**

##### Registration date

2018-02-11, 1396/11/22

##### Registrant information

###### Name

tahere rezaeian

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2218 0039

###### Email address

ta.rezaeian@uswr.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-02, 1397/01/13  
**Expected recruitment end date**  
2018-07-21, 1397/04/30  
**Actual recruitment start date**  
2018-04-07, 1397/01/18  
**Actual recruitment end date**  
2018-09-10, 1397/06/19  
**Trial completion date**  
2018-09-10, 1397/06/19

#### **Scientific title**

The effects of treating myofascial trigger points of neck using the techniques of dry needling and soft tissue release on the clinical feature of patients with migraine headache

#### **Public title**

Effects of dry needling and soft tissue release in treatment of migraine patients

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

1. A neurologist selected the study subjects based on IHS criteria for diagnosis of migraine. 2. The patients in this study were between the ages of 25 and 55 years old The patients with migraine were examined to find any active trigger points in UT, SCM, sub-occipital muscles . The presence of active trigger points was confirmed if "1- There was an area of focal muscle tenderness that was activated by palpation and that, when activated, referred pain replicating the patient's headache complaint. 2- There was a jump sign that was the characteristic behavioral response to pressure on a trigger point" . One diagnostic test in particular, the flexion-rotation test, is said to determine C1-2 dysfunction .Patient was supine position. With the subject relaxed and the cervical spine is fully flexed with the occiput resting against the examiners. The head is then rotated to the left and the right. If firm resistance is perceived, pain provoked and range is limited before the expected end range .The normal range is reported at 44-45 degrees, therefore, the test is positive when the range of motion is more than 10 degrees from the normal range.Studies have shown that migraine has a small effect on the range of motion during this test, but this test shows the presence or absence of cervicogenic headache and this test can use for Differential Diagnosis between migraine headache and cervicogenic headache.The positive test indicates a cervicogenic headache

##### **Exclusion criteria:**

history of cervical disc herniation, unusual migraine, heart failure, pulmonary failure, kidney failure, liver failure, circulation failure, diabetes mellitus patients who were using opioid prophylaxis, anti -depressant, anti-anxiety drugs subjects who were pregnant or breastfeeding and Those who having trigger point therapy within the past month before the study The patients, who underwent DN, had no contraindication for needling such as local infection, pregnancy with threatened abortion, taking anticoagulants

#### **Age**

From **25 years** old to **55 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

#### **Sample size**

Target sample size: **60**  
More than 1 sample in each individual  
Number of samples in each individual: **20**  
20 subjects per group  
Actual sample size reached: **68**  
More than 1 sample in each individual  
Actual sample size in each individual: **20**  
20 subjects per group

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

Block Randomization

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

Double-blind study will be done, in this way, the allocation of people to the groups and the assessment of patients are done by people who are unaware of the status of the grouping of patients. Treatment is provided by a specialist physiotherapist and evaluated by a collaborator.

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

#### **Secondary Ids**

empty

#### **Ethics committees**

##### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of the University of Social Welfare and Rehabilitation Sciences

##### **Street address**

Koodakyar St., Daneshjoo Blvd, Velenjak, Tehran, Iran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1985713834

#### **Approval date**

2016-06-19, 1395/03/30

#### **Ethics committee reference number**

## Health conditions studied

### 1

#### Description of health condition studied

Migraine patients

#### ICD-10 code

I67.8

#### ICD-10 code description

Other specified cerebrovascular diseases

## Primary outcomes

### 1

#### Description

1-Headache frequency

#### Timepoint

Before, After and 1month follow up

#### Method of measurement

Daily note form

### 2

#### Description

2-Headache intensity

#### Timepoint

Before, After and 1month follow up

#### Method of measurement

Daily note form

### 3

#### Description

3-Headache duration

#### Timepoint

Before, After and 1month follow up

#### Method of measurement

Daily note form

### 4

#### Description

Number of drug consumption

#### Timepoint

Before, After and 1month follow up

#### Method of measurement

Daily note form

## Secondary outcomes

### 1

#### Description

1.Pressure pain threshold

#### Timepoint

Before, After and 1month follow up

#### Method of measurement

Algometer

### 2

#### Description

2-Muscle thickness

#### Timepoint

Before, After and 1month follow up

#### Method of measurement

Ultrasonography

### 3

#### Description

3-Range of motion

#### Timepoint

Before, After and 1month follow up

#### Method of measurement

Goniometer

### 4

#### Description

4-Neck disability index

#### Timepoint

Before, After and 1month follow up

#### Method of measurement

Neck disability index questionnaire

### 5

#### Description

5-Head disability index

#### Timepoint

Before, After and 1month follow up

#### Method of measurement

Head disability index questionnaire

### 6

#### Description

6-Pain intensity

#### Timepoint

Before, After and 1month follow up

#### Method of measurement

Visual analog scale

## Intervention groups

### 1

#### Description

Intervention group: Dry needling

#### Category

Rehabilitation

### 2

#### Description

Intervention group: Soft tissue release

#### Category

Rehabilitation

**3**

**Description**

Control group: Placebo control

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Visual analog scale, Algometer, Ultrasonography, Goniometer, Neck disability index questionnaire and

**Full name of responsible person**

Dr.Mansour Hedayat

**Street address**

Shiraz Shahid Chamran Avenue - Student Square - next to Amin Ali Pharmacy - Eram Building - Third Floor

**City**

Shiraz

**Province**

Fars

**Postal code**

7185796184

**Phone**

+98 71 3229 8382

**Email**

tahere.rezaiyan@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Hamidreza Khanakeh

**Street address**

kodakyar Ave., daneshjo Blvd.,Evin.,Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985713834

**Phone**

+98 21 2218 0050

**Fax**

**Email**

rd@uswr.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Tahere Rezaeian

**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

kodakyar Ave., daneshjo Blvd.,Evin,Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985713834

**Phone**

+98 21 2218 0039

**Email**

tahere.rezaiyan@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Tahere Rezaeian

**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

kodakyar Ave., daneshjo Blvd.,Evin,Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

7185796184

**Phone**

+98 21 2218 0039

**Email**

tahere.rezaiyan@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Tahere Rezaeian

**Position**

Tehran

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

Koodakyar St., Daneshjoo Blvd, Velenjak, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

7185796184

**Phone**

+98 21 2218 0039

**Email**

tahere.rezaiyan@gmail.com

## 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**

Some of the data, such as information about the consequences, can be shared

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

Starting the access period: 6 months after publication the results

**To whom data/document is available**

Researchers working in academic and academic institutions

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

Only statistical analyses can be used to find treatment for improvement of patients

**From where data/document is obtainable**

Applicants can be guided by email authors

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

First, they will email the authors of the study and we will be answered within a week

**Comments**