

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### A Comparative Study of Sonographic and Clinical Parameters of Trigger Point of the Upper Fiber of the Trapezius Muscle Following " Dry Needling " and " Intramuscular Electrical Stimulation " (IMES) through Needle.

#### Protocol summary

##### Study aim

The aim of this study is to comprehensively evaluate the effectiveness and comparison of each of the two interventions in needling and intramuscular electrical stimulation using objective tools such as sonographic parameters as well as clinical parameters on the symptoms of the upper trapezius muscle trigger points.

##### Design

Clinical trial with control group, parallel groups, single-blind, randomized, on 30 patients. Balanced blocks randomization are used.

##### Settings and conduct

School of Rehabilitation, Shahid Beheshti University of Medical Sciences

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.Active trigger points in the upper trapezius muscle 2. Pain associated with the trigger point of the upper trapezius muscle above 3 on the VAS scale 3. Age: 18-30 years. Exclusion criteria: 1. Injections or other treatments for trigger points since one month before the research. 2. History of muscle diseases such as fibromyalgia and myopathy. 3. Malignancy or exposed to infection. 4. Central and peripheral neurological disorders. 5. Skin damage in the trigger point area. 6. Taking sedatives before and during treatment. 7. Radicular pain and history of neck and shoulder surgery. 8. History of bad response to acupuncture or dry needling. 9. Pregnancy. 10. Taking anticoagulants. 11. Significant fear of dry needling. 12. Vascular disease. 13. Diabetes. 14. History of migraine. 15. History of accident or trauma in the relevant areas.

##### Intervention groups

1. Intramuscular Electrical Stimulation 2. Dry Needling

##### Main outcome variables

Pain; Pain pressure threshold; Neck range of motion, Disability rate; Ultrasonic parameters

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170616034567N2**

Registration date: **2020-09-11, 1399/06/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-09-11, 1399/06/21**

Update count: **0**

##### Registration date

2020-09-11, 1399/06/21

##### Registrant information

##### Name

monavar hadizdeh

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7754 2057

##### Email address

hadizadeh-m@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-05, 1399/06/15

##### Expected recruitment end date

2020-12-05, 1399/09/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

A Comparative Study of Sonographic and Clinical Parameters of Trigger Point of the Upper Fiber of the Trapezius Muscle Following " Dry Needling " and " Intramuscular Electrical Stimulation " (IMES) through Needle.

### Public title

Investigation of the effects of intramuscular electrical stimulation on trigger points

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Active trigger points in the upper trapezius muscle Pain associated with the upper trapezius muscle trigger point above 3 based on the VAS scale which is considered as moderate pain. Age: 18-35 years.

#### Exclusion criteria:

Perform injections or other treatments for trigger points in the period of one month before the research. Previous history of muscle diseases such as fibromyalgia and myopathy. Malignancy or patients prone to infection. Central and peripheral neurological disorders. Skin damage in the trigger point area. Taking sedatives before and during treatment. Radicular pain and history of neck and shoulder surgery. Previous history of bad response to acupuncture or dry needling. Pregnancy. Taking anticoagulants. Significant fear of dry needling. Vascular disease. Diabetes. History of migraine. History of accident or trauma in the relevant areas.

### Age

From **18 years** old to **35 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Data analyser

### Sample size

Target sample size: **30**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Random method: balanced block randomization  
Allocation concealment: sealed envelope  
How to do randomization: To randomize by balanced block randomization method, we do the following: Intervention group code: A Control group code: B  
1. Due to having two groups, the designated blocks are four (AABB). The group codes in these blocks can be designed in six ways. 1(AABB), 2(BBAA), 3(ABAB), 4(BABA), 5(ABBA), 6(BAAB)  
Y. Depending on the size of the sample of thirty, 8 of these blocks, which are 32 codes in total, are randomly placed next to each other. 3. Then, each of these codes, which represents the treatment group of each patient, is placed in a sealed envelope, and these envelopes are placed next to each other. These steps will be performed by another person and the lead researcher does not

know each person's group until the moment of intervention.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

In this study, the data analyzer is blinded because they do not know each patient belongs to which intervention group. To do this, the names of the groups are coded (intervention group: A and control group: B) and data analyzer will not know the code of each group.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee in Biomedical Research, Shahid Beheshti University of Medical Sciences

##### Street address

No. 2, Shahid Beheshti University of Medical Sciences, Evin Ave, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

#### Approval date

2020-08-09, 1399/05/19

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1399.480

## Health conditions studied

### 1

#### Description of health condition studied

Upper trapezius muscle trigger point

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Before, after and one month after treatment

#### Method of measurement

by Visual Analogue Scale

## 2

### **Description**

Pain pressure threshold

### **Timepoint**

Before, after and one month after treatment

### **Method of measurement**

by algometer

## 3

### **Description**

Neck range of motion

### **Timepoint**

Before, after and one month after treatment

### **Method of measurement**

lateral flexion and rotation by goniometer

## 4

### **Description**

Disability

### **Timepoint**

Before, after and one month after treatment

### **Method of measurement**

by Neck Disability Index

## 5

### **Description**

Ultrasonic parameters

### **Timepoint**

Before, after and one month after treatment

### **Method of measurement**

by sonography device

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: intramuscular electrical stimulation, The intervention in this group was intramuscular electrical stimulation in which the patient was placed lying on his stomach. The muscle is then touched and the needle is inserted into the trigger point and the therapist's fingers. In the next step, the cathode electrode is connected to the needle and the other pole is placed on the spinous process of the seventh vertebra of the neck by a circular electrode. This will apply the current to the trigger point for 10 minutes. At the end of the mentioned period, first the current intensity is zero and then the device is removed from the patient's body and the needle is removed.

#### **Category**

Treatment - Other

## 2

### **Description**

Control group: Dry Needling Group, In this group of patients, needling will be performed for the patient as in the previous group. In this way, after the needle enters the trigger point, the needle will move in and out. This process will continue until the insertion and removal of the twitch needle is no longer seen at the trigger point 10 times, then the needle will leave the individual muscle.

### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Faculty of rehabilitation, Shahid Beheshti University of medical sciences

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

Mohammad mohsen Roostaei

##### **Street address**

Faculty of rehabilitations, Damavand Ave

##### **City**

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##### **Postal code**

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##### **Email**

hadizade.mahsa1992@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Shahid Beheshti University of Medical Sciences

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

Afshin Zarghi

##### **Street address**

SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

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+98 21 2243 9770

##### **Email**

Intl\_office@sbmu.ac.ir

#### **Grant name**

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

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

Yes

**Title of funding source**

Shahid Beheshti University of Medical Sciences

**Proportion provided by this source**

20

**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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Monavar Hadizadeh

**Position**

PhD Candidate

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific inquiries

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Professor

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## Person responsible for updating data

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available