

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of Single Session Intramuscular Electrical Stimulation through Dry Needling on Pain and Dysfunction Following Trigger Points in Upper Trapezius Muscle

#### Protocol summary

##### Summary

Background and Objective: Myofascial Pain Syndrome (MPS) is a common disorder of musculoskeletal system. About one third of people with musculoskeletal disorders have been identified as the MPS. The MPS cause by trigger points. Variety of treatment methods is applied to care the MPS and relative disorders. The purpose of this study is to investigate effects of single session Intramuscular Electrical Stimulation (IMES) using dry needling on pain and dysfunction following trigger points in upper trapezius muscle. Methods: This study is a randomized, double-blind, placebo-controlled clinical trial. 30 volunteers with active trigger points in upper trapezius randomly will be divided into two main groups including the IMES (15 female) and placebo (15 female). In the IMES group, trigger points on the affected side identify and will be injected through dry needling. Then, a burst current (2 Hz frequency, 200 $\mu$ s pulse width) apply through the needles while electrical current steadily increase to meet a pain free contraction. In placebo group, procedure is exactly similar but no electrical stimulation apply following Intramuscular Dry Needling (IDN). Pain sensation (by Visual Analog Scale=VAS), and Pain Pressure Threshold (PPT) ( by algometer), range of motion (by goniometer) and disability (by Neck Disability Index=NDI) were measured before application and exactly after treatment and followed again one week later . All outcome measures assesse by another researcher do not have details about the groups. In this study, researcher that measure outcome measure do not know details about intervention in each groups. Patients are not informed about the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017061634567N1**

Registration date: **2017-08-05, 1396/05/14**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-08-05, 1396/05/14

##### 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

Investigator

##### Expected recruitment start date

2017-09-06, 1396/06/15

##### Expected recruitment end date

2017-11-06, 1396/08/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of Single Session Intramuscular Electrical Stimulation through Dry Needling on Pain and Dysfunction Following Trigger Points in Upper Trapezius Muscle

**Public title**

Effects of Intramuscular Electrical Stimulation on Upper Trapezius Trigger Points Treatment

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: 1. Active trigger points with specific bundle in upper trapezius muscle 2. The pain associated with the trigger point of the upper trapezius muscle be higher than 3 based on the VAS scale, which is considered as moderate pain. 3. Age 18-40 4. Do not give injections or other treatments for trigger points within a month before the study. 5. No history of muscle diseases such as fibromyalgia and myopathy. 6. No malignancy or patients susceptible to infection. 7. Not having central and peripheral neurological disorders. 8. Not having radical pain and history of neck surgery. 9. have no previous history of bad response to acupuncture or dry needling. 10. No pregnancy 11. Do not use anticoagulants. 12. No significant fears from the dry needling. 13. Not having vascular disease. 14. Not having diabetes. 15. Not having a history of migraine. exclusion criteria: 1. Withdrawal of cooperation by the patient. 2. Discomfort and intolerance method applied to the patient. 3. Incidence of abnormal reactions during dry needling and treatment.

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

In this study for randomization will be used balanced block randomization.

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee in Tehran University of Medical Sciences

**Street address**

Tehran, Keshavarz Blvd, Central building of Tehran University of Medical Sciences

**City**

tehran

**Postal code**

**Approval date**

2017-05-03, 1396/02/13

**Ethics committee reference number**

IR.TUMS.FNM.REC.1396.2216

**Health conditions studied**

1

**Description of health condition studied**

Trigger Points in Upper Trapezius Muscle

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

pain

**Timepoint**

before application, exactly after treatment and one week after treatment

**Method of measurement**

by visual analog scale

2

**Description**

Pain Pressure Threshold

**Timepoint**

before application, exactly after treatment and one week after treatment

**Method of measurement**

by algometer

3

**Description**

range of motion

**Timepoint**

before application, exactly after treatment and one week after treatment

**Method of measurement**

by goniometer

**Secondary outcomes**

## 1

### Description

disability

### Timepoint

before application and week after treatment

### Method of measurement

by Neck Disability Index

## Intervention groups

## 1

### Description

Intervention group: The intervention in this group is intramuscular electrical stimulation. The patient is in prone, while the hands are placed next to the body and the head is in the midline. For a patient's comfort, a roll under the forehead is used. The muscle is needled with a pincer palpation. The needle is inserted perpendicular to the skin and directed towards the practitioner's finger. In the next step, the cathode electrode is connected to the needle and the other is placed by a circular electrode on the spinous process of seventh vertebra of neck. Then, a burst current (2 Hz frequency, 200µs pulse width) apply through the needles while electrical current steadily will be increased to meet a pain free contraction. The treatment is continued for a period of ten minutes.

control(placebo): In placebo group procedure is exactly the same but there is no electrical stimulation under dry needling. The treatment is continued for a period of ten minutes.

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Physiotherapy Clinic of Tehran University of Medical Sciences

#### Full name of responsible person

Siamak Bashardoust Tajali

#### Street address

Faculty of Rehabilitation, piche shemiran st, Enghelab Ave, Tehran, Iran

#### City

tehran

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

monavar hadizadeh

#### Street address

Faculty of Rehabilitation, Piche shemiran st, Enghelab

Ave, tehran, iran

#### City

tehran

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Tehran University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

empty

### Domestic or foreign origin

empty

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

monavar hadizadeh

#### Position

master student

#### Other areas of specialty/work

#### Street address

Faculty of Rehabilitation, Piche Shemiran st, Enghelab Ave, Tehran, Iran

#### City

tehran

#### Postal code

#### Phone

+98 21 7753 3939

#### Fax

#### Email

hadizadeh-m@razi.tums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Siamak Bashardoust Tajali

#### Position

Assistant Professor

#### Other areas of specialty/work

#### Street address

Faculty of Rehabilitation, Piche Shemiran st, Enghelab Ave, Tehran, Iran

#### City

Tehran

#### Postal code

**Phone**

+98 2177685105253

**Fax****Email**

s\_bashardoust@sina.tums.ac.ir

**Web page address****Phone**

+98 21 7753 3939

**Fax****Email**

hadizadeh-m@razi.tums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Monavar Hadizadeh

**Position**

master student

**Other areas of specialty/work****Street address**

Faculty of Rehabilitation, Piche Shemiran st, Enghelab Ave, Tehran, Iran

**City**

Tehran

**Postal code****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*