

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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	know each person's group until the moment of intervention.
Scientific title	Blinding (investigator's opinion)
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.	Single blinded
Public title	Blinding description
Investigation of the effects of intramuscular electrical stimulation on trigger points	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.
Purpose	Placebo
Treatment	Not used
Inclusion/Exclusion criteria	Assignment
Inclusion criteria:	Parallel
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.	Other design features
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.	Secondary Ids
Age	empty
From 18 years old to 35 years old	Ethics committees
Gender	1
Both	Ethics committee
Phase	Name of ethics committee
N/A	Ethics Committee in Biomedical Research, Shahid Beheshti University of Medical Sciences
Groups that have been masked	Street address
Data analyser	No. 2, Shahid Beheshti University of Medical Sciences, Evin Ave, Tehran
Sample size	City
Target sample size: 30	Tehran
Randomization (investigator's opinion)	Province
Randomized	Tehran
Randomization description	Postal code
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) ۲. 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	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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

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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
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Master
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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