Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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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) 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 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 known 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

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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 Roostaee
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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
PhD Candidate

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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Professor

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PhD Candidate

Latest degree
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Physiotherapy

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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