Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

The comparison of short-term effects of Transcutaneous Electrical Nerve Stimulation (TENS) and dry needling on pain, disability and pressure pain threshold in subjects with trigger points in upper trapezius muscle

Protocol summary

Study aim
The purpose of the present study is to compare the short-term effects of Transcutaneous Electrical Nerve Stimulation (TENS) with dry needling on pain, disability and pressure pain threshold in subjects with trigger points in upper trapezius muscle

Design
A randomized, controlled, clinical trial with parallel groups and blinded outcome assessment and data analyzer,45 patients

Settings and conduct
This study will be conducted at sevvom Shaaban Physiotherapy Clinic. 45 subjects will be randomly divided into three groups(A (TENS), B (dry needle) and C (control group)) using random numbers table.The first group, in addition to trapezius muscle stretching exercise will also receive TENS for ten sessions. The second group will receive dry needles for three sessions in addition to exercise for two weeks and the control group will receive exercise only. The examiner assesses the outcome once before treatment and once after the intervention after two weeks. The examiner is unaware of what treatment each patient will receive. data are given to analyst as B, A and C data, and the analyst is unaware of which data belongs to which group.

Participants/Inclusion and exclusion criteria
Subjects between 18-50 yrs of age with reading and writing ability who had trigger points in the upper trapezius muscle and with nonspecific neck pain with a score of at least 3 on the visual analog scale if exclusion criteria are not met are include in the study.

Intervention groups
Patients will be divided into three groups using a random number table. The first group, in addition to trapezius muscle stretching exercise will also receive TENS for ten sessions. The second group will receive dry needles for three sessions in addition to exercise for two weeks and the control group will receive exercise only.

Main outcome variables
Severity of pain; Pressure Pain Threshold; Neck Disability Index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200204046376N1**
Registration date: **2020-10-28, 1399/08/07**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-28, 1399/08/07**
Update count: **0**

Registration date
2020-10-28, 1399/08/07

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-16, 1399/07/25

Expected recruitment end date
2021-01-14, 1399/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of short-term effects of Transcutaneous Electrical Nerve Stimulation (TENS) and dry needling on pain, disability and pressure pain threshold in subjects with trigger points in upper trapezius muscle

Public title

The comparison of Transcutaneous Electrical Nerve Stimulation (TENS) and dry needling in subjects with trigger points in upper trapezius muscle

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Subjects between 18-50 yrs of age. Subjects who have the ability to read and write. Subject with trigger points in the upper trapezius muscle based on the Travel and Simons diagnistic criteria. Individuals with nonspecific neck pain with a score of at least 3 on the visual analog scale and originating in the trigger points of the upper trapezius muscle, which may also be referred to the area between the scapula and the shoulder.

Exclusion criteria:

Fibromyalgia syndrome with specialist physician diagnosis. Postural abnormalities including severe kyphosis or scoliosis where the spine is not in its natural alignment. Congenital deformity in the neck. Taking anticoagulants or using corticosteroids. Use of analgesics within 48 hours before intervention. Alcohol and Drug Use. Cognitive and communication disorders. Sense disorder in the treated area (neck and shoulder area). Symptoms of Radiculopathy. Received treatment for trigger points of the trapezius muscle over the past three months. Degenerative problems of the neck and shoulder joints. History of surgery in the neck or shoulder area. Contraindication to the use of dry needles such as fear of needles and local infection and pregnancy with the risk of miscarriage and menstruation and a serious medical problem. Diagnosis of neurological disorder by a specialist physician. Malignancy and systemic diseases.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a table of random numbers, we select 45 numbers and record the numbers in order, then each of the clients is assigned one of these numbers in order. Then the last two digits of the numbers, if it is between ..., the person will be in group A, if it is between ..., the person will be in group B and if it is between ..., the person will be in group C.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person who assesses the outcome before and after the intervention is completely unaware of the grouping of patients and in which group they are in. This person only performs this task during the study And it has no other involvement in the study process. The person analyzing the data is also unaware of which data belongs to the group and will be given the data as group A, B and C data.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Building No. 4, Hezar Jarib St., Isfahan University of Medical Sciences

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2020-09-23, 1399/07/02

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.392

Health conditions studied

1

Description of health condition studied

subjects with trigger points in upper trapezius muscle

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain intensity score based on visual analog scale
Timepoint
Pain intensity score will be measured once before the start of the intervention and once after the end of the treatment period ie 2 weeks later.
Method of measurement
Visual Analog Scale

2

Description
Pressure Pain Threshold score
Timepoint
Pressure Pain Threshold score will be measured once before the start of the intervention and once after the end of the treatment period ie 2 weeks later.
Method of measurement
Digital Algometer

3

Description
Neck disability score based on Neck Disability Index Questionnaire
Timepoint
Neck Disability Score will be measured once before the start of the intervention and once after the end of the treatment period ie 2 weeks later.
Method of measurement
Neck Disability Index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Group A will receive TENS (Burst type Asymetrical rectangular biphasic pulse electrical current) with 100 Hz frequency and 250 microsecond pulse duration for ten sessions (5 days a week) over two weeks and each session will receive TENS for 20 minutes. The intensity of the electrical current increases to the extent that the patient has a strong sense but no muscle contraction. This current is applied by a channel and two electrodes where the negative electrode is placed on the trigger point of upper trapezius muscle and the positive electrode at the insertion of muscle to the acromion. stimulator710 P Plus (Novin company) will be used for electrical stimulation, in addition, stretching exercise for the trapezius muscle is fully taught to patients, with emphasis on doing the exercises three times a day, each time ten repetition and maintaining a stretching state for 15 seconds.
Category
Treatment - Other

2

Description
Intervention group:Group B is treated with three sessions of dry needling for two weeks. Before starting the technique, the most sensitive trigger point is detected and Its position on the skin is determined. A needle with a diameter of 0.3 mm and a length of 30 mm, in both prone and supine position on both anterior and posterior sides is insrted after disinfecting the site with alcohol, so that the point is pressed firmly with the thumb and forefinger of the non-dominant hand. In order to obtain a local twitch response, the needle is inserted perpendicular to the muscle tissue for a maximum of 10 times within 10 seconds at a frequency of 1 Hz, also stretching exercise for the trapezius muscle is fully taught to patients, with emphasis on doing the exercises three times a day, each time ten repetition and maintaining a stretching state for 15 seconds.
Category
Treatment - Other

3

Description
Control group: stretching exercise for the trapezius muscle is fully taught to patients, with emphasis on doing the exercises three times a day, each time ten repetition and maintaining a stretching state for 15 seconds.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sevom shaban physiotherapy clinic
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Esfahan University of Medical 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
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Person responsible for updating data

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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

No - There is not 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

Demographic information and the main outcome of the study are shared after being unidentifiable

When the data will become available and for how long

Access starts after the study has been placed in databases.

To whom data/document is available

Researchers working in academic centers and private centers and other researchers

Under which criteria data/document could be used

Researchers who intend to study systematic review or meta-analysis

From where data/document is obtainable

Seyyed Mohsen Mirbod (responsible author), via email address

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

The request email and the purpose of requesting the information should be sent to the responsible author, then the responsible author will give them the requested information.

Comments