

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The Effect of Acupuncture like TENS in the Treatment of cervical Myofascial trigger points

Protocol summary

Study aim

Investigation the effect of low-frequency electrical stimulation on neck trigger points

Design

This study is a double-blind, single-center clinical trial with parallel groups and a control group that will be conducted on 60 patients with neck pain complaints. Patients will be divided into 3 groups by block randomization using sealed envelopes. Outcome measures will be measured before the treatment, after 5 sessions, and after 3 months.

Settings and conduct

This study will be conducted at Firoozgar Hospital in Tehran in patients referred to physical medicine and rehabilitation clinic with neck pain complaints. Then, patients will be randomly assigned into 3 groups by block randomization using sealed envelopes. Participants do not know what type of Transcutaneous electrical nerve stimulation (TENS) is being used for them. Since the TENS device is administered by a physiotherapist and the screen will not be visible to the patient or physician, the physician will be blind to grouping. The outcome assessor, who is the lead researcher, will be blind to the grouping when evaluating outcomes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Complications of neck pain and painful points and palpable bands. Exclusion Criteria: Obvious mental illness, Cervical Radiculopathy, Joint degenerative disease, Systemic diseases, History of surgery in the neck, History of fracture in the neck, pregnancy.

Intervention groups

First group receives Transcutaneous electrical nerve stimulation (TENS) with 2-10 Hz frequency and 200-250 microsecond (ms) pulse (PD) in addition to specific exercises. Second group receives TENS with 120 Hz frequency and 80-100 ms PD duration in addition to specific exercises. Control group receives placebo TENS in addition to specific exercises.

Main outcome variables

Pain, Performance

General information

Reason for update

Study scheduling update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150219021139N12**

Registration date: **2018-04-15, 1397/01/26**

Registration timing: **prospective**

Last update: **2020-06-12, 1399/03/23**

Update count: **1**

Registration date

2018-04-15, 1397/01/26

Registrant information

Name

Safoora Ebadi

Name of organization / entity

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Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-16, 1397/01/27

Expected recruitment end date

2019-04-16, 1398/01/27

Actual recruitment start date

2018-04-16, 1397/01/27

Actual recruitment end date

2019-04-16, 1398/01/27
Trial completion date
2019-08-15, 1398/05/24

Scientific title

The Effect of Acupuncture like TENS in the Treatment of cervical Myofascial trigger points

Public title

The Effect of TENS on neck trigger points

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Complications of neck pain and having painful points and palpable bands in neck

Exclusion criteria:

Obvious mental illness Neck radiculopathy Joint degenerative disease Systemic diseases History of surgery in the neck History of fracture in the neck pregnancy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization using sealed envelopes into 3 groups

Blinding (investigator's opinion)

Double blinded

Blinding description

1- Participants Do not know which kind of TENS they are receiving. 2- Since the TENS apparatus will be applied by the physical therapist assistant, and the monitor of the device would not be in either patient's or therapist's sight, the therapist is blind to the allocation. 3- The outcome assessor who is the main investigator, would not be aware of the allocation when assessing the patients in the measuring time points.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway. Tehran, 1449614535, IRAN

City

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Province

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Postal code

1449614535

Approval date

2017-11-03, 1396/08/12

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9511524007

Health conditions studied

1

Description of health condition studied

myofascial pain

ICD-10 code

M79.1

ICD-10 code description

Myalgia

Primary outcomes

1

Description

pain

Timepoint

Before treatment, after treatment, after three months from the end of treatment

Method of measurement

Visual Scale of Pain

2

Description

function

Timepoint

Before treatment, after treatment, after three months from the end of treatment

Method of measurement

Shortness-disability questionnaire for arm, shoulder and hand and cervical problem questionnaire

Secondary outcomes

1

Description

Cervical range of motion
Timepoint
Before treatment, after the end of treatment, after three months of the end of treatment
Method of measurement
Universal Goniometer

2

Description
Pressure pain threshold
Timepoint
Before treatment, after the end of treatment, after three months of the end of treatment
Method of measurement
Algometer

Intervention groups

1

Description
First group receives TENS with 2-10 Hz frequency and 200-250 microsecond pulse duration in addition to specific exercises.
Category
Rehabilitation

2

Description
Second group receives TENS with 120 Hz frequency and 80 - 100 microsecond pulse duration in addition to specific exercises.
Category
Rehabilitation

3

Description
Control group: Control group receives placebo TENS (on device without output) in addition to specific exercises.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
Dr. Safara Ebadi
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Sponsors / Funding sources

1

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Name of organization / entity
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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
Iran 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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Dr.Safara Ebadi
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Assistant professor
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Physiotherapy
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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Deidentified Individual Participant Data Set can be
shared

When the data will become available and for how long

starting after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

in case other researchers want to perform additional
analysis on the data other than published their
application will be discussed in an authors meeting.

From where data/document is obtainable

via investigator's email ebadi.s@iums.ac.ir

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

applicant should email his/her identification
specifications and the reason she is applying.

Comments