Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
Iran 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
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

Street address

Physical Medicine and Rehabilitation Department,Firouzgar Hospital,Behafarin St.,Karim Khane zand St.

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Sponsors / Funding sources

1

Sponsor

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

Iran University of Medical Sciences

Full name of responsible person

Dr.Safora Ebadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

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Position
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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