

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of high frequency Transcutaneous Electrical Nerve Stimulation (TENS) with low frequency TENS on pain, and physical discomforts in patients with muscle tension dysphonia

Protocol summary

Study aim

Comparison of the effect of high frequency Transcutaneous Electrical Nerve Stimulation (TENS) with low frequency TENS on pain, and physical discomforts in patients with muscle tension dysphonia

Design

Clinical trial with two arm parallel group with 26 patients

Settings and conduct

This clinical trial will be performed on 26 patients with muscle tension dysphonia in Amir A'lam Hospital in Tehran. The presence of MTD in patients will be detected by an ear, nose and throat physician and a speech and language pathologist. Patients will be divided into two groups, one low-frequency transcutaneous electrical nerve stimulation therapy group and another will receive high-frequency transcutaneous electrical nerve stimulation. The assessment of musculoskeletal pain and vocal tract discomfort will be used to investigate the treatment outcome.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The presence of muscle tension dysphonia The age range between 18 to 45 years
Exclusion criteria: Smoking Pregnancy A history of various types of laryngeal malignancies A history of laryngeal surgery A history of chemotherapy and radiotherapy in the head and neck area

Intervention groups

The low-frequency transcutaneous electrical nerve stimulation group and high-frequency transcutaneous electrical nerve stimulation group

Main outcome variables

Musculoskeletal pain, Vocal tract discomfort

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190203042605N2**

Registration date: **2019-08-20, 1398/05/29**

Registration timing: **prospective**

Last update: **2019-08-20, 1398/05/29**

Update count: **0**

Registration date

2019-08-20, 1398/05/29

Registrant information

Name

Seyed Abolfazl Tohidast

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of high frequency Transcutaneous Electrical Nerve Stimulation (TENS) with

low frequency TENS on pain, and physical discomforts in patients with muscle tension dysphonia

Public title

Comparison of the effect of high frequency TENS with low frequency TENS on pain, and physical discomforts in MTD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The presence of muscle tension dysphonia The age range between 18 to 45 years

Exclusion criteria:

Smoking Pregnancy A history of various types of laryngeal malignancies A history of laryngeal surgery A history of chemotherapy and radiotherapy in the head and neck area

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, each participant picks a number between 1 and 26 from the bag: odd numbers were assigned to group 1 (Low-frequency TENS) and even numbers were assigned to group 2 (High-frequency TENS).

Blinding (investigator's opinion)

Single blinded

Blinding description

In the present study, the participants are kept blind and will not be aware of the frequency type of electrical stimulation which be used.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Research Affairs, Main Campus of Semnan University

of Medical Sciences, Amirkabir Square, Semnan, Iran

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35147-99442

Approval date

2019-07-16, 1398/04/25

Ethics committee reference number

IR.SEMUMS.REC.1398.80

Health conditions studied

1

Description of health condition studied

Muscle Tension Dysphonia

ICD-10 code

R49.0

ICD-10 code description

Dysphonia

Primary outcomes

1

Description

Musculoskeletal pain

Timepoint

Before treatment and immediately after treatment

Method of measurement

Visual analogue scale

2

Description

Vocal tract discomfort

Timepoint

Before treatment and immediately after treatment

Method of measurement

Vocal Tract Discomfort scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Transcutaneous electrical nerve stimulation with low frequency in 10 sessions each one lasting 20 minutes

Category

Rehabilitation

2

Description

Intervention group: Transcutaneous electrical nerve

stimulation with high frequency in 10 sessions each one lasting 20 minutes

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir A'lam Hospital

Full name of responsible person

Seyed Abolfazl Tohidast

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Seyed Abolfazl Tohidast

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

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Fax**Email**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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