Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Iran (Islamic Republic of)
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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
City
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Province
Semnan
Postal code
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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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