

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 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)

##### Phone

+98 23 3365 4180

##### Email address

a.tohidast@semums.ac.ir

#### 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

Semnan

### 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

**Street address**

District 12, Saadi St, Tehran

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**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Parviz Kookhaie

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Research Affaires, Main Campus of Semnan University of Medical Sciences, AmirKabir Square, Semnan, Iran

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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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Speech and Language Therpay Deptment, Rehabilitation Faculty, Semnan University of Medical Sciences, 5 km. of Damghan Road, Semnan, Iran

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**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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Ph.D.

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## Person responsible for updating data

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### Contact

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

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**Phone**

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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