

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Comparison of the effect of Laryngeal Manual Therapy with Transcutaneous Electrical Nerve Stimulation on Acoustic Voice Parameters, Vocal Tract Discomfort, and Musculoskeletal Pain in Patients with Muscle Tension Dysphonia

#### Protocol summary

##### Study aim

Comparison of the effect of Laryngeal Manual Therapy with Transcutaneous Electrical Nerve Stimulation in Patients with Muscle Tension Dysphonia

##### Design

Clinical trial with two arm parallel group with 20 patients

##### Settings and conduct

This clinical trial will be performed on 20 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 laryngeal manual therapy group and another will receive transcutaneous electrical nerve stimulation. The assessment of voice characteristics, vocal tract discomfort, and musculoskeletal pain 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 No Smoking Exclusion criteria: 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 laryngeal manual therapy group and transcutaneous electrical nerve stimulation group

##### Main outcome variables

Voice characteristics, Vocal tract discomfort, Musculoskeletal pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190203042605N1**

Registration date: **2019-06-13, 1398/03/23**

Registration timing: **prospective**

Last update: **2019-06-13, 1398/03/23**

Update count: **0**

##### Registration date

2019-06-13, 1398/03/23

##### 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

2019-06-22, 1398/04/01

##### Expected recruitment end date

2019-09-23, 1398/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of Laryngeal Manual Therapy with Transcutaneous Electrical Nerve Stimulation on

Acoustic Voice Parameters, Vocal Tract Discomfort, and Musculoskeletal Pain in Patients with Muscle Tension Dysphonia

35147-99442

**Approval date**

2019-05-21, 1398/02/31

**Ethics committee reference number**

IR.SEMUMS.REC.1398.047

**Public title**

Comparison of the effect of Laryngeal Manual Therapy with Transcutaneous Electrical Nerve Stimulation on Voice Parameters, and Physical discomforts in Patients with Muscle Tension Dysphonia

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

The presence of muscle tension dysphonia The age range between 18 to 45 years No Smoking

**Exclusion criteria:**

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**

*No information*

**Sample size**

Target sample size: **20**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**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**

**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**

Voice characteristics of patients with MTD

**Timepoint**

Before treatment and immediately after treatment

**Method of measurement**

Acoustic voice parameters evaluation, Auditory-perceptual assessment of voice

**2**

**Description**

Vocal tract discomfort

**Timepoint**

Before treatment and immediately after treatment

**Method of measurement**

Vocal Tract Discomfort scale

**3**

**Description**

Musculoskeletal pain

**Timepoint**

Before treatment and immediately after treatment

**Method of measurement**

Visual analogue scale

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

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

**Category**

Rehabilitation

**2**

**Description**

Control group: Laryngeal manual therapy 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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Tehran, District 12, Saadi St

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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

**Street address**

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

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Semnan University of Medical Sciences

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**Person responsible for updating data****Contact****Name of organization / entity**

Semnan University of Medical Sciences

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Sciences, 5 km. of Damghan Road, Semnan, Iran

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**Province**

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**Postal code**

35131-38111

**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