

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Investigation the Effect of transcutaneous electrical stimulation voice therapy (TESVT ) on Voice features in Patients with Muscular Tension Dysphonia (MTD )

#### Protocol summary

##### Study aim

to evaluation of the Effect of transcutaneous electrical stimulation voice therapy (TESVT ) on Voice features in Patients with Muscular Tension Dysphonia (MTD )

##### Design

In this study, only one group of patients with MTD is involved. To identify and diagnose participants with MTD, an ENT physician which assisted in the study recruited. then The patients will be referred to the same hospital once they have been diagnosed.

##### Settings and conduct

This study is an experimental clinical trial study on 18 patients with MTD who are candidates for acoustic therapies in the speech therapies of Qa'im and Imam Reza hospitals from Mashhad University of Medical Sciences . The presence of MTD in the patient will be detected in collaboration with an ENT physician. The voice of each patient will be evaluated before and after the treatment using Acoustic, aerodynamic, Auditory-Perceptual (GRBAS) and Self-Assessment (VHI) scales.

##### Participants/Inclusion and exclusion criteria

The presence of dysphonia caused by MTD muscle tension for patients is necessary.

##### Intervention groups

This treatment involves the use of TES on the sternocleidomastoid muscle, cricothyroid and both sides of hyoid bone in MTD patients for 12 sessions of 20 minutes (two weekly sessions).

##### Main outcome variables

Acoustic voice features (fundamental frequency, jitter, shimmer, noise ratio to harmonic), The characteristics of the aerodynamics (maximum MPT and s / z ratio) Auditory-Perceptual Features (Degree, Violence, Self-Pollution, Weakness, Scramble) and Voice handicap Index (Total score)

#### General information

##### Reason for update

##### Acronym

TESVT

##### IRCT registration information

IRCT registration number: **IRCT20181217042016N1**

Registration date: **2019-02-23, 1397/12/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-02-23, 1397/12/04**

Update count: **0**

##### Registration date

2019-02-23, 1397/12/04

##### Registrant information

##### Name

hamide ghaemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3881 4351

##### Email address

ghaemih@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-07-21, 1398/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**  
Investigation the Effect of transcutaneous electrical stimulation voice therapy (TESVT ) on Voice features in Patients with Muscular Tension Dysphonia (MTD )

**Public title**  
Investigation the Effect of transcutaneous electrical stimulation voice therapy (TESVT ) on Voice features in Patients with Muscular Tension Dysphonia (MTD )

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
☐ The age range is 18 to 55 years ☐ No Smoking ☐ Non-pregnancy ☐ Lack of intubation history within three months before entering the research ☐ Lack of a history of various types of laryngeal malignancies ☐ Lack of history of surgery in the larynx ☐ Lack of history of chemotherapy and radiotherapy in the head and neck area ☐ The presence of dysphonia caused by muscle tension MTD  
**Exclusion criteria:**  
☐ Infections of the respiratory system, such as colds, during the assessment process or during the respiratory tract

**Age**  
From **18 years** old to **55 years** old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **18**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethics committee of Mashhad university of medical sciences

##### Street address

No. 5, Sremi 19 Ave, Kowsar Blvd., Mashhad town

**City**  
Mashhad

**Province**  
Razavi Khorasan

**Postal code**  
7881236228

**Approval date**  
2018-11-17, 1397/08/26

**Ethics committee reference number**  
IR.MUMS.REC.1397.212

## Health conditions studied

### 1

#### Description of health condition studied

muscular tension dysphonia disorder

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

the voice features of MTD patients

#### Timepoint

one week before and one week after treatment

#### Method of measurement

the patients voice assessed by acoustic, aerodynamic, auditory perceptual evaluation and voice handicap index.

## Secondary outcomes

### 1

#### Description

without second outcome

#### Timepoint

without second outcome

#### Method of measurement

without second outcome

## Intervention groups

### 1

#### Description

Intervention group: For the intervention , the transcataneous electrical stimulation with two pads is used. Pads are placed on the sternocleidomastoid , cricothyroid muscles and two sides of the hyoid bone for 20 minutes.

#### Category

Rehabilitation

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Qaem and Imam Reza hospital

**Full name of responsible person**

hamide ghaemi

**Street address**

No. 5, Saremi 19 Ave, Kowsar Blvd, Mashhad Town.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

88123462827

**Phone**

+98 51 3881 4351

**Email**

hamideghaemi@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Mashhad university of medical sciences. in front of  
Daneshgah 18 Ave, Daneshgah Blvd, Mashhad Town.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

8812346282

**Phone**

+98 51 3882 3255

**Email**

tafaghodim@mums.ac.ir

**Grant name**

research deputy of Mashhad university of medical  
sciences

**Grant code / Reference number****Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

hamide ghaemi

**Position**

associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Speech therapy

**Street address**

No. 5, Saremi 19 Ave, Kowsar Blvd, Mashhad Town

**City**

Mashhd

**Province**

Razavi Khorasan

**Postal code**

8812346282

**Phone**

+98 51 3881 4351

**Email**

hamideghaemi@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

hamide ghaemi

**Position**

associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Speech therapy

**Street address**

No. 5, Saremi 19 Ave, Kowsar Blvd, Mashhad town.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

8812346282

**Phone**

+98 51 3881 4351

**Email**

hamideghaemi@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hamide Ghaemi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Speech therapy

**Street address**

No.19,Saremi Ave., Kowsar Blvd., Mashhad.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

8812346282

**Phone**

+98 51 3881 4351

**Fax****Email**

ghaemih@mums.ac.ir

**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**

Only part of the information, such as the main outcome information, can be shared.

**When the data will become available and for how long**

during 6 month after publishing the results.

**To whom data/document is available**

Only available to scholars working in scientific and academia.

**Under which criteria data/document could be used**

no changes can be made

**From where data/document is obtainable**

Refer to the correspond author and executor of this research.

**What processes are involved for a request to access data/document**

By submitting a request by email, to the research executor .

**Comments**