

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 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