

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of manual Circumlaryngeal therapy with combination of manual Circumlaryngeal therapy and Transcutaneous Electrical Nerve Stimulation in Muscle tension dysphonia patients

Protocol summary

Study aim

The additional effects of Transcutaneous Electrical Nerve Stimulation(TENS) to manual therapy in people with Muscle tension dysphonia

Design

A clinical trial with a control group, randomized, double-blind

Settings and conduct

Two electrodes are placed on the parapharyngeal area on the neck. The device is lit only for TENS and manual therapy, but not for manual therapy. After twenty minutes, both groups receive manual therapy. Patients are unaware of their treatment group. The only manual therapist is aware of the treatment group.

Participants/Inclusion and exclusion criteria

inclusion criteria: diagnosis of muscle tension dysphonia; Voice problem for more than three months; 45>age>20. exclusion criteria: patient with pace maker; History of respiratory problems; Skin scars on the front of the neck ; Laryngeal congenital problems; History of surgery on the neck or larynx ; History Tracheostomy; history of cervical problems; history of neurological problems

Intervention groups

Control group: At each of ten treatment sessions, the "control group" is asked to lie on the bed. Then two Electrodes are placed on the parapharyngeal part of the neck. In the "control group" the device will not turn on. After 20 minutes, the Electrodes are removed. After this step, the "control group" receives manual therapy. Intervention group: At each of ten treatment sessions, the "control group" is asked to lie on the bed. Then two Electrodes are placed on the parapharyngeal part of the neck. In the "Intervention group" the device turns on. After 20 minutes, the Electrodes are removed. After this step, the "Intervention group" receives manual therapy.

Main outcome variables

RMS in electromyography dysphonia severity index

Nordic musculoskeletal symptoms questionnaire
palpation score observation stroboscopic

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181125041752N1**

Registration date: **2019-05-25, 1398/03/04**

Registration timing: **retrospective**

Last update: **2019-05-25, 1398/03/04**

Update count: **0**

Registration date

2019-05-25, 1398/03/04

Registrant information

Name

Qobad Shabani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 87 3524 0597

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-15, 1397/08/24

Expected recruitment end date

2019-01-14, 1397/10/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of manual Circumlaryngeal therapy with combination of manual Circumlaryngeal therapy and Transcutaneous Electrical Nerve Stimulation in Muscle tension dysphonia patients

Public title
The effect of Transcutaneous Electrical Nerve Stimulation and manual Circumlaryngeal therapy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 People with muscle tension dysphonia Voice problem more than three months Lack of viral or bacterial laryngitis No voice therapy received in the past or at the same time
Exclusion criteria:
 People with hormonal and thyroid gland problems People with history of respiratory problems People with lesion on the front of the neck People with a history of congenital laryngeal problems People with a history of laryngeal or thyroid surgery People with a history of tracheostomy People with a history of neurological problems People with history of cervical problems People with history of temporomandibular joint disorder

Age
From **19 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple random method, It is written on 11 A4 paper, letter A (to determine the manual Circumlaryngeal therapy group), and 11 other A4 papers B (to determine the Circumlaryngeal therapy and Transcutaneous Electrical Nerve Stimulation group), and each of the references is asked to select one of these two Pick up

Blinding (investigator's opinion)
Double blinded

Blinding description
Before manual therapy in each session, the patient is asked to lie on the bed and cover his eyes with an blindfold. Two electrodes for device Transcutaneous Electrical Nerve Stimulation are placed on the parapharyngeal area on the neck. The devices in manual therapy group is placed on the neck, but the devices is not turned on. Two groups are asked to keep their blindfold. After twenty minutes, both groups receive

manual treatment. Only the therapist is aware of which of the patients receive radiation. The main investigator is not aware of which of the patients fall into any of the treatment groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Jundi shapour University
Street address
 Golestan Highway
City
 Ahwaz
Province
 Khuzestan
Postal code
 61357-15794
Approval date
 2018-11-12, 1397/08/21
Ethics committee reference number
 IR.AJUMS.REC.1397.603

Health conditions studied

1

Description of health condition studied
 Musle tension dysphonia
ICD-10 code
 R49.0
ICD-10 code description
 Dysphonia

Primary outcomes

1

Description
 RMS score in electromyography
Timepoint
 at the beginning of the study (before the intervention) and at the end of the tenth session
Method of measurement
 Surface Electromyography

2

Description
 Dysphonia Severity Index
Timepoint

at the beginning of the study (before the intervention)
and at the end of the tenth session
Method of measurement
Dysphonia Severity Index questionnaire

3

Description
musculoskeletal pain severity

Timepoint
at the beginning of the study (before the intervention)
and at the end of the tenth session

Method of measurement
Nordic musculoskeletal symptoms questionnaire

4

Description
Paralaryngeal muscle tension

Timepoint
at the beginning of the study (before the intervention)
and at the end of the tenth session

Method of measurement
Morrison indexg

5

Description
glottal condition

Timepoint
at the beginning of the study (before the intervention)
and at the end of the tenth session

Method of measurement
Video stroboscopic

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: combination of manual
Circumlaryngeal therapy and Transcutaneous Electrical
Nerve Stimulation

Category
Rehabilitation

2

Description
Control group: manual Circumlaryngeal therapy and
placebo

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Musculoskeletal Rehabilitation Center
Full name of responsible person
Negin Moradi
Street address
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33133 -61357
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohamad badavi
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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
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person

Negin Moradi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

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Latest degree

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

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Masters student

Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

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