

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison between manual therapy with combined manual therapy and drug therapy on voice characterizes of patients with muscle tension disorder

Protocol summary

Study aim

Investigating the effectiveness of the combination of herbal medicine and laryngeal manipulation on the treatment of voice disorders in people with musculoskeletal dysphonia and comparing it with laryngeal manipulation

Design

This is an intervention study of the clinical trial type with a control group, with parallel groups, double-blind, randomized, phase 3 on 34 patients.

Settings and conduct

The work is two-way blind. In such a way that the evaluator and the patient are not aware of the treatment groups, and also the intervention group of drug therapy and laryngeal manipulation and the control group only perform laryngeal manipulation, it should be noted that the place of intervention is the Rehabilitation Faculty of Jundishapur University of Ahvaz .

Participants/Inclusion and exclusion criteria

1- participant have a history of musculoskeletal dysphonia. 2- participant have no history of speech therapy. 3- participant have a cognitive level suitable for taking medicine

Intervention groups

Both the control and sampling groups have musculoskeletal dysphonia, with the difference that different treatments will be applied to them.

Main outcome variables

Age; gender; type of treatment; ease of pronunciation; Bad voice index score; Assessment of voice discomfort

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221214056813N1**

Registration date: **2022-12-26, 1401/10/05**

Registration timing: **prospective**

Last update: **2022-12-26, 1401/10/05**

Update count: **0**

Registration date

2022-12-26, 1401/10/05

Registrant information

Name

mostafa behroozi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-13, 1401/10/23

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between manual therapy with combined manual therapy and drug therapy on voice characterizes of patients with muscle tension disorder

Public title

Investigating the effect of drug therapy on laryngitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Presence of muscle tension dysphonia Not having a history of speech therapy Having appropriate cognitive levels to take medicine
Exclusion criteria:
 Presence of neurologic disorder Presence of Gastric Acid Reflux

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
To implement the simple random method, you can use the table of random numbers and consider even and odd numbers and assign each of the two treatments A (to determine the manual therapy group) and B (to determine the manual therapy and drug therapy group) to an even number and The person continued the process until each group reached 17 people, in this study, even and odd numbers were selected using R software and through the generation of random numbers using a uniform distribution in the interval (0,1).

Blinding (investigator's opinion)
Double blinded

Blinding description
It should also be mentioned that the therapist and clients are unaware of the group therapy and the work is blind. In this way, the evaluator is not aware of the treatment groups (manual therapy and drug therapy are performed by another therapist).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Jundishapur Ahvaz University

Street address

Ground floor, Research and Technology Vice-Chancellor, Jundishapur University of Medical Sciences and Medical Services

City

Ahvaz

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Postal code

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Approval date

2022-12-10, 1401/09/19

Ethics committee reference number

IR.AJUMS.REC.1401.445

Health conditions studied

1

Description of health condition studied

Voice disorder

ICD-10 code

R49.0

ICD-10 code description

Dysphonia

Primary outcomes

1

Description

Inflammation of the larynx

Timepoint

Measurement of laryngitis on the first day and 30 days after the start of treatment

Method of measurement

Using a laryngeal imaging device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the composition of echinopes medicinal plant for 30 days and twice a day in the amount of 10 mg, which will be made by the Faculty of Pharmacy of Jundi Shapur University of Ahvaz, and laryngeal massage for 10 sessions and twice a week by a speech therapist

Category

Rehabilitation

2

Description

Control group: larynx manipulation for 10 sessions and twice a week by a speech therapist

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Rehabilitation, Jundishapur University,
Ahvaz

Full name of responsible person

Negin moradi

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Sponsors / Funding sources

1

Sponsor

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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

Mostafa behroozi

Position

Senior student of speech therapy at Jundi Shapur
University, Ahvaz

Latest degree

Bachelor

Other areas of specialty/work

Speech therapy

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Person responsible for updating data

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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 plan for sharing these data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available