

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The additional effects of infrared light to manual therapy in people with Muscle tension dysphonia

Protocol summary

Study aim

The additional effects of infrared light to manual therapy in people with Muscle tension dysphonia

Design

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

Settings and conduct

In each session, each patient is asked to lie on the bed and cover his eyes with an blindfold. Two NEW Dual Infrared and Red Light Therapy Speeds Healing 120 leds are placed on the parapharyngeal area on the neck. The device is lit only for Low-Level Laser Therapy (LLLT) and manual therapy, but not for manual therapy. After twenty minutes, both groups receive manual therapy. Patients are unaware of their treatment group. The main researcher is unaware of the patient's treatment group. The only manual therapist is aware of the treatment group.

Participants/Inclusion and exclusion criteria

inclusion criteria: diagnosis of muscle tension dysphonia; pain in the laryngeal region; age > 20. exclusion criteria: pregnant; patient with pace maker; Patient with cancer if there is a possibility of metastasis; Epilepsy or seizure; Hormonal disorders; Cervical dysfunction; History of surgery on the neck or larynx; Cardiovascular problems.

Intervention groups

Control group: A group of patients with MTD who receive only manual therapy. Intervention group: A group of patients with MTD who receive manual treatment and Low-Level Laser Therapy (LLLT)

Main outcome variables

First Formant (acoustic resonance of vocal tract (related to height of vowel)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171230038149N1**

Registration date: **2018-07-06, 1397/04/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-06, 1397/04/15**

Update count: **0**

Registration date

2018-07-06, 1397/04/15

Registrant information

Name

Negin Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3743 1013

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The additional effects of infrared light to manual therapy in people with Muscle tension dysphonia

Public title

Effects of infrared light and manual therapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

diagnosis of Muscle tension dysphonia pain in the laryngeal region age>20

Exclusion criteria:

pregnant patient with pace maker Patient with cancer if there is a possibility of metastasis Epilepsy or seizure Hormonal disorders neck vessel problems History of surgery on the neck or larynx Cardiovascular problems

Age

From 20 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

A simple random method, It is written on 10 A4 paper, letter A (to determine the manual treatment group), and 10 other A4 papers B (to determine the manual treatment group and Low-level Laser therapy (LLLT), 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 NEW Dual Infrared and Red Light Therapy Speeds Healing 120 leds 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

Factorial

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

Khouzestan

Postal code

61357-15794

Approval date

2017-12-16, 1396/09/25

Ethics committee reference number

IR . AJUMS. REC. 1396 .712

Health conditions studied

1

Description of health condition studied

Musle tension dysphonia

ICD-10 code

R49

ICD-10 code description

Voice and resonance disorders

Primary outcomes

1

Description

First Formant

Timepoint

at the beginning of the study (before the intervention) and at the end of the eighth session and two weeks after the last session.

Method of measurement

praat software

2

Description

second formant

Timepoint

at the beginning of the study (before the intervention) and at the end of the eighth session and two weeks after the last session.

Method of measurement

praat softwave

Secondary outcomes

empty

Intervention groups

1

Description

Control group: At each of eight treatment sessions, the "control group" is asked to lie on the bed and cover their eyes with blindfolds. Then two infrared devices are placed on the parapharyngeal part of the neck. In the "control group" the device will not be switched and patients will not receive radiation. After 20 minutes, the devices are removed. Then, patients can remove the blindfolds. After this step, the "control group" receives manual therapy. The patient should lie on the bed and the skilled therapist starts the manual therapy. manual therapy includes massages that cause relaxation of the laryngeal muscles and improve the quality of the voice. When the massages is performed, the patient is asked to sustain a vowel and judge the improvement of the quality of the voice.

Category

Rehabilitation

2

Description

Intervention group: At each of the eight treatment sessions, the "intervention group" is also asked to lie on the bed and cover their eyes with an blindfolds. Two devices are placed in the parapharyngeal part of the neck. In the "intervention group", the device is switched and the patient receives infrared radiation. This radiation causes warming and increased blood circulation and removes poisons through sweat. After 20 minutes, the devices are removed. Then, patients can remove the blindfolds. The patient should lie on the bed and the skilled therapist starts the manual therapy. manual therapy includes massages that cause relaxation of the laryngeal muscles and improve the quality of the voice. When the massages is performed, the patient is asked to sustain a vowel and judge the improvement of the quality of the voice.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Musculoskeletal Rehabilitation Center

Full name of responsible person

Negin Moradi

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Golestan Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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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

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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