Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effectiveness of Early Voice Therapy Protocol on Vocal Function, Self- Assessment of Vocal Function and Quality of Life for Patients with Early Laryngeal Carcinoma after Transoral Laser Microsurgery (TLM)

Protocol summary

Study aim

evaluate the effectiveness of early voice therapy on vocal function, self-assessment of vocal function and quality of life in patients with Early laryngeal carcinoma after laser surgery

Design

A randomized controlled clinical trial on 48 patients with early laryngeal cancer undergoing laser surgery with inclusion criteria and referred to the speech rehabilitation ward of Amira'lam Hospital in Tehran using available sampling method. Assignment to the intervention and control groups is done by Blocked randomization method.

Settings and conduct

This study is performed in Amira'lam Hospital of Tehran.The study is also conducted as a single blind. patients in both groups do not know which group they are in.

Participants/Inclusion and exclusion criteria

Inclusion criteria: infection with unilateral or bilateral malignant tumors of the Glottis area, being in stage zero,1 or 2 tumor growth, not receiving other oncological treatments (such as radiation, hormones and chemotherapy) before or at the same time with the research period, maximum 3 days Completion of laser surgery; Exclusion criteria: advanced laryngeal cancer, diagnosis of malignancy in other parts of the larynx and body except the Glottis.

Intervention groups

Participants in the intervention group underwent voice rehabilitation with a symptomatic approach (consisting of change of loudness, focus, pitch inflections, chewing, Yawn - Sigh, Lip Roll and Tongue Trill, Glottal Fry and breathing exercises) with voice hygiene recommendations in ten 30-minute sessions is given twice a week (a total of 300 minutes / 5 hours), while the control group will be presented in parallel, during which time only voice hygiene recommendations will be provided.

Main outcome variables

Values of acoustic analysis, aerodynamics and auditory parameters; ranking of videolaryngoscopic image parameters; self-assessment score of vocal function; quality of life score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210131050187N1**
Registration date: **2021-06-15, 1400/03/25**
Registration timing: **prospective**

Last update: **2021-06-15, 1400/03/25**
Update count: **0**

Registration date

2021-06-15, 1400/03/25

Registrant information

Name

Arezoo Hasanvand

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01
Expected recruitment end date
2021-07-23, 1400/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of Early Voice Therapy Protocol on Vocal Function, Self- Assessment of Vocal Function and Quality of Life for Patients with Early Laryngeal Carcinoma after Transoral Laser Microsurgery (TLM)

Public title
Multidimensional evaluation of the effectiveness of Early Voice Therapy Protocol on the voice of patients with Early Laryngeal Carcinoma after Transoral Laser Microsurgery (TLM)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in research Age range 18 to 65 years Infection with unilateral or bilateral malignant tumors of the Glottis Area Being at stage zero, 1 or 2 tumor growth No metastasis to lymph nodes and other parts of the body Not receiving other oncological treatments (such as radiation, hormones and chemotherapy) before or at the same time as the research period Do not participate in other courses of voice therapy after oncology treatment to improve voice disorder A maximum of 3 days have elapsed since the completion of the laser surgery Ability to read and write No cognitive problems No diabetes No drug use Do not use alcohol
Exclusion criteria:
Advanced laryngeal cancer Receiving parallel and simultaneous other oncological treatments such as radiotherapy and chemotherapy The presence of malignant cells in other parts of the larynx and body except the pelvis
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
In the first step to create a randomization, individuals are first placed in one of the treatment or control groups using the block randomization method performed by someone other than the researcher; The block randomization method in this research is performed in such a way that first we assign code to all eligible people to enter the study and in the next step, using the table of random numbers to determine the direction to move on this table. For treatment and control groups, we consider two blocks of equal size and 12 (including 12 people in the intervention group and 12 people in the control group) and then randomly close their eyes with a finger on a point. We place the rows and columns of the table at the intersection and numbers that are equal to or less than the sample size are seen and random sequences are created for these blocks. In the next step, to execute the random sequence generated on the subjects, we will use the random allocation concealment method so that the assigned group is not known before the individual is assigned. In this study, using non-transparent containers sealed with the same weight and shape of each random sequences created on a registration card and cards are inserted into the cans respectively. In order to maintain a random sequence, the numbering on the outer surface of the boxes is done in the same way.Eventually, the lids of the cans are sealed, and according to the order in which eligible people enter the study, one of the cans is opened in order, and the assigned group of the participant is revealed.
Blinding (investigator's opinion)
Single blinded
Blinding description
To blind the research, a speech therapist from outside the current research project with at least 5 years of clinical / research experience and trained to work with laboratory programs and devices to assess treatment outcomes and collect data on variables in the three domains of vocal function, Self-assessment of vocal function and quality of life is used. In the present study, data analysis is performed by a person other than the main researcher and analyzes the study data. Also, the participants of the two groups do not know which group they are in. In other words, the subjects will be given only the necessary information about the general objectives and conditions of the study, and all participants were unaware that they were in the treatment or control group, and at the start of the project, only in order and in the form of Individuals receive a attendance schedule from the researcher. It should be noted that participants do not communicate with each other and their presence for evaluation and treatment is done individually and separately from each other.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the University of Social Welfare and Rehabilitation Sciences

Street address
Kodakyar Ave., Daneshjo Blvd., Evin, University of Social Welfare and Rehabilitation Sciences

City
Tehran

Province
Tehran

Postal code
1985713871

Approval date
2021-05-12, 1400/02/22

Ethics committee reference number
IR.USWR.REC.1400.002

Health conditions studied

1

Description of health condition studied
Laryngeal Carcinoma

ICD-10 code
C32.0

ICD-10 code description
Malignant neoplasm of glottis

Primary outcomes

1

Description
Jitter (Frequency Perturbation)

Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention

Method of measurement
Acoustic analysis of voice signal with Multidimensional Voice Program software

2

Description
Shimmer (Amplitude Perturbation)

Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention

Method of measurement
Acoustic analysis of Voice signal with Multidimensional Voice Program software

3

Description
Noise to Harmonic Ratio

Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention

Method of measurement
Acoustic analysis of Voice signal with Multidimensional Voice Program software

4

Description
Relative Average Perturbation

Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention

Method of measurement
Acoustic analysis of Voice signal with Multidimensional Voice Program software

5

Description
Amplitude Perturbation Quotient

Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention

Method of measurement
Acoustic analysis of Voice signal with Multidimensional Voice Program software

6

Description
Voice Turbulence Index

Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention

Method of measurement
Acoustic analysis of Voice signal with Multidimensional Voice Program software

7

Description
Soft Phonation Index

Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention

Method of measurement
Acoustic analysis of Voice signal with Multidimensional Voice Program software

8

Description
Degree of Voicelessness

Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention

Method of measurement
Acoustic analysis of Voice signal with Multidimensional Voice Program software

9

Description
Cepstral Peak Prominence
Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention
Method of measurement
Acoustic analysis of Voice signal with Praat software

10

Description
Smoothed Cepstral Peak Prominence
Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention
Method of measurement
Acoustic analysis of Voice signal with Praat software

11

Description
Maximum Phonation Time
Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention
Method of measurement
Calculate the duration of sustain phonation of vowel /a/ with Stopwatch Application

12

Description
Vital Capacity
Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention
Method of measurement
Spirometry

13

Description
Phonation Quotient
Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention
Method of measurement
The score obtained by dividing the Vital capacity parameters by the Maximum Phonation Time

14

Description
Dysphonia Severity Index
Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention
Method of measurement
The weighted score of the parameters of Maximum Phonation Time, highest Frequency, lowest Intensity and Jitter of voice signal

15

Description
Vocal Folds edge
Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention
Method of measurement
View and evaluate videolaryngoscopic images

16

Description
Glottic Closure Pattern
Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention
Method of measurement
View and evaluate videolaryngoscopic images

17

Description
Amplitude of Vibration
Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention
Method of measurement
View and evaluate videolaryngoscopic images

18

Description
Phase Symmetry
Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention
Method of measurement
View and evaluate videolaryngoscopic images

19

Description
Muscle Tension Patterns
Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention
Method of measurement
View and evaluate videolaryngoscopic images

20

Description
Total Severity of perceptual voice disorder
Timepoint
At the beginning of the intervention, the end of the intervention, one month after the end of the intervention
Method of measurement
score in the Persian Consensus Auditory Perceptual Evaluation of Voice test

21

Description

Self assessment of Vocal Function

Timepoint

At the beginning of the intervention, the end of the intervention, one month after the end of the intervention

Method of measurement

Voice Handicap Index 30 Score

22

Description

Quality of Life

Timepoint

At the beginning of the intervention, the end of the intervention, one month after the end of the intervention

Method of measurement

Iranian Voice Quality of Life

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the Intervention group, received early voice therapy intervention consisting of Symptomatic Voice Therapy (including chewing, yawn - sigh, Lip Roll and tongue Trill, pitch change, vocal focus change, pitch change, chin chirping, and breathing exercises) with training voice hygiene twice a week, for a total of 10 sessions of 30 minutes for 5 weeks (a total of 300 minutes / 5 hours of voice therapy) and are re-evaluated after this process.The order and process of presenting the training in the treatment sessions is such that the therapist teaches voice hygiene tips at the beginning of the session and has an overview of the exercises of the previous session and the correctness of their implementation, then teaches the new method. In the first session, after providing voice hygiene recommendations, the therapist teaches loudness level and exercises on level 2 of change of loudness method during continuous speech and reading. In the second session, the therapist again provides voice hygiene recommendations and reviews the practice of the previous session, which included the technique of change of loudness, then teaches how to change the focus of voice. In the third session, the therapist first reviews the exercises of the previous sessions (including changing the loudness and changing the focus of the voice) and then teaches the breathing exercises and the pitch inflections method. At the beginning of the fourth session, the therapist reviews the exercises of the previous sessions (including the practice of pitch inflections and change of loudness methods) with the patient, and then deals with breathing exercises and chewing method. The fifth session begins with a review of the exercises of the previous sessions (including chewing and pitch inflections methods) and ends with breathing exercises and Yawn - Sigh training.At the beginning of the sixth session, the exercises of the previous sessions (including the methods of chewing and Yawn - Sigh) are reviewed, then breathing exercises and the Lip Roll and Tongue Trill are taught. In the seventh session, the exercises of the previous sessions (including Lip Roll, tongue Trill, Yawn - Sigh methods) are reviewed, followed by breathing exercises and training and practice of the Glottal Fry method.In the eighth session, the therapist first reviews the exercises of the previous sessions (including Glottal Fry and Yawn - Sigh methods), then practices breathing exercises and the method of Lip Roll and Tongue Trill with the patient. In the ninth session, the previous exercises were reviewed in such a way that the method of pitch inflections with the change of loudness and the method of chewing (at the level of words and sentences) with the Glottal Fry and the method of Yawn - Sigh with the production of the word were practiced and repeated with the patient. In the tenth session, Lip Roll and Tongue Trill with Pitch Inflections methods, chewing with Yawn - Sigh methods, the Glottal Fry with a change of loudness is practiced and repeated with the patient. It should be noted that treatment sessions are held individually. The researcher will also make four 15-minute phone calls with the participants of the treatment group one month after the end of the treatment with intervals of 7 days to follow up and inform about their general condition, and then the individuals will be re-evaluated at the end of this course.

Category

Rehabilitation

2

Description

Control group: The therapist provides the patient with the necessary training in a number of cases: including awareness of behaviors related to the use of voice, such as talking for long periods of time, laughing and crying out loud, clearing the throat as usual, screaming and shouting; Adjusting environmental conditions such as avoiding talking and being in crowded, dry environments containing pollutants and smoke; Improving diet and lifestyle: Avoid high-calorie and fatty foods, caffeine, tobacco, alcohol and adequate rest and sleep. For voice hygiene training twice a week for a total of ten 30-minute sessions for 5 weeks (300 minutes). The researcher will also make four 15-minute phone calls at 7-day intervals with participants of both treatment and control groups to follow up and be informed of their general condition, and then individuals. They will be re-evaluated at the end of this course.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir A'lam Hospital Complex

Full name of responsible person

Akbar Darouei

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy of University of Social welfare and Rehabilitation Sciences
Full name of responsible person
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Kodakyar Ave., Daneshjo Blvd., Evin, Research deputy of University of Social Welfare and Rehabilitation Sciences
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Email
hrkhkh@yahoo.com
Web page address
https://www.uswr.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy of University of Social welfare and Rehabilitation 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
University of social welfare and rehabilitation sciences
Full name of responsible person
Akbar Darouei
Position
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Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Arezoo Hasanvand
Position
Phd Candidate of Speech Therapy
Latest degree
Master
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