Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation the effect of endoscopic medialization thyroplasty using autologous nasal septal cartilage graft in patients with unilateral vocal fold paralysis on voice features: A before and after clinical trial

Protocol summary

Study aim

Investigating the effect of medialization of endoscopic thyroplasty using nasal septum cartilage autograft in unilateral vocal cord paralysis patients on voice characteristics

Design

Phase 2 clinical trial (without control group) on 15 patients, Non-randomized and unblinded

Settings and conduct

Patients with unilateral vocal cord paralysis refering to the Otorhinolaryngology Clinic of Qaem Hospital in Mashhad will be included with informed consent. Before the surgery, 2 weeks, 2 and 6 months after the surgery, indirect laryngoscopy will be performed (in the speech therapy center of Ava) and the auditory-perceptual and acoustic evaluation of the voice, and also the evaluation of the voice disability index and voice of the patients during speech (with a standard unit sound recording device) is performed by a speech and language pathologist at the mentioned intervals.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Unilateral vocal fold paralysis, age over 18 years Exclusion criteria: Unwillingness to participate in the study Saddle nose Bilateral vocal fold paralysis History of septoplasty Uncontrolled head and neck malignancy External laryngeal trauma Laryngeal neoplasm Severe laryngeal stenosis Central nervous system disorder Severe cardiopulmonary disorder that the patient cannot tolerate surgery

Intervention groups

All patients with unilateral vocal fold paralysis undergo endoscopic medialization thyroplasty with nasal septal cartilage autograft and the voice characteristics of the patients before and after the intervention are compared. (Due to the pilot study and the unavailability of previous injectable and prosthetic methods -because of embargo - it is not possible to have a separate control group at this time.)

Main outcome variables

Stridor, aspiration, auditory-perceptual characteristics of voice, Voice handicap index, acoustic characteristics of voice

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231003059595N1**
Registration date: **2023-11-11, 1402/08/20**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-11, 1402/08/20**
Update count: **0**

Registration date

2023-11-11, 1402/08/20

Registrant information

Name

zahra valipour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-11, 1402/08/20

Expected recruitment end date

2024-07-10, 1403/04/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the effect of endoscopic medialization thyroplasty using autologous nasal septal cartilage graft in patients with unilateral vocal fold paralysis on voice features: A before and after clinical trial

Public title
Evaluation the effect of endoscopic medialization thyroplasty using nasal septal cartilage graft on voice features
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Unilateral vocal fold paralysis Age : above 18y
Exclusion criteria:
Unwillingness to participate in the study Saddle nose Bilateral vocal fold paralysis History of septoplasty Uncontrolled head and neck malignancy External laryngeal trauma Laryngeal neoplasm Severe laryngeal stenosis Central nervous system disorder Severe cardiopulmonary disorder that the patient cannot tolerate surgery
Age
From **18 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **15**
Randomization (investigator's opinion)
N/A
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 Faculty of Medical Sciences
Street address
Medicine Faculty, Azadi Sq.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Approval date
2023-04-11, 1402/01/22
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1402.015

Health conditions studied

1

Description of health condition studied
Paralysis of vocal cords and larynx
ICD-10 code
J38. 00
ICD-10 code description
Paralysis of vocal cords and larynx, unspecified

Primary outcomes

1

Description
Stridor
Timepoint
Before surgery and at intervals of 2 weeks, 2 months, and 6 months after surgery
Method of measurement
Clinical examination of the patient

2

Description
Aspiration
Timepoint
Before surgery and at intervals of 2 weeks, 2 months, and 6 months after surgery
Method of measurement
Clinical examination of the patient

3

Description
Auditory-perceptual characteristics of sound
Timepoint
Before surgery and at intervals of 2 weeks, 2 months, and 6 months after surgery
Method of measurement
GRBAS scale is used to evaluate audio-perception of sound, which describes Grade, Roughness, Breathiness, Asthenia and Straining in 4 modes (0=no defect, 1=mild defect, 2=moderate defect and 3=severe defect). This index is an expert-oriented index. For this purpose, the voice sample recorded from the patient with the help of

headphones for the speech therapist is played according to the mentioned 4-degree scale.

4

Description
Voice handicap index
Timepoint
Before surgery and at intervals of 2 weeks, 2 months, and 6 months after surgery
Method of measurement
Questionnaire will be filled in three functional, physical and emotional parts in these patients. This questionnaire has 30 questions, and it is provided to the patient and completed by them in each of the assessment phases.

5

Description
Acoustic characteristics of sound
Timepoint
Before surgery and at intervals of 2 weeks, 2 months, and 6 months after surgery
Method of measurement
Acoustic evaluations include many things that are evaluated in this research. All acoustic evaluations will be done by a speech therapist with the help of PRAAT software. The types of acoustic features are mentioned below. 1- Maximum vocalization time (MPT): to evaluate the maximum ability of a person. It is measured based on seconds using a stopwatch in three times and the average number of times is recorded. 2- Jitter: disturbance of frequency and amplitude of frequency disturbance 3- Shimmer: disturbance of amplitude of oscillation 4- Noise to harmonic ratio (NHR): to check the sound quality 5- Average fundamental frequency (F0): indicator of the usual pitch 6- Closed quotient: percentage of duration The time of a glottis cycle when the vocal folds are closed and the airflow does not pass.

Secondary outcomes

1

Description
Dyspnea
Timepoint
Before surgery and at intervals of 2 weeks, 2 months, and 6 months after surgery
Method of measurement
Based on patient history and clinical presentation using NYHA criteria

2

Description
Saddle nose
Timepoint
Before surgery and at intervals of 2 weeks, 2 months, and 6 months after surgery
Method of measurement
Clinical examination of the patient

3

Description
Septal perforation
Timepoint
Before surgery and at intervals of 2 weeks, 2 months, and 6 months after surgery
Method of measurement
Clinical examination of the patient

4

Description
Surgical site infection
Timepoint
Before surgery and at intervals of 2 weeks, 2 months, and 6 months after surgery
Method of measurement
Clinical examination of the patient

5

Description
Chondral graft failure
Timepoint
Before surgery and at intervals of 2 weeks, 2 months, and 6 months after surgery
Method of measurement
Clinical examination of the patient

Intervention groups

1

Description
In operating room conditions and under general anesthesia, after prep and drape in sterile conditions, a hemitransfix incision is made at the mucocutaneous junction to remove the septum. The mucoperichondral flaps are raised bilaterally to expose the quadriangular cartilage. Then, mucoperiosteal flaps are raised on the vomer and maxillary crest to create maximum exposure. A vertical incision is made 1.5 cm posterior to the caudal border of the quadriangular cartilage. Another cartilaginous incision is made parallel to the dorsum, about 1.5 cm below the dorsum. The cartilage of the septum will be removed by disarticulating it from the maxillary crest, vomer and perpendicular plate of the ethmoid bone. In order to prevent damage to the bridge of the nose and create a saddle nose, at least one centimeter of cartilage will be preserved in the dorsal and lower part of the nose. The incision is repaired using Vicryl thread and quilting sutures are placed on both sides of the septum. Nasal pack is performed to maintain the mucoperichondrium to the nasoseptal cartilage and prevent hematoma formation. Then, using direct microlaryngoscopy, vocal folds are observed. After carpool injection, a lateral cordotomy is performed with a medial micro-flap and a pocket is created in the thyroarytenoid muscle complex and vocalis. It will be measured with a ruler from the anterior commissure to the vocal process. Then, according to the obtained size, one or more cartilage strips, measured in length and two

to three millimeters in width, are placed separately in the envelope from front to back, so that optimal medialization is achieved based on the transverse and vertical planes of the vocal fold. Then the incision will be sutured with 0.6 Vicryl thread. Once homeostasis is established, the operation will be terminated.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Ehsan Khadivie
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
Ehsan Khadivi
Position
Associate professor
Latest degree
Subspecialist
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Person responsible for updating data

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Full name of responsible person
Zahra Valipour

Position
ENT Resident

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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 further information

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