

# 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 referring 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)

##### Phone

+98 51 3858 3864

##### Email address

zahra.valipour74@gmail.com

##### 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 Khadivi

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Ahmadabad st.

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9176699199

**Phone**

+98 51 3840 0001

**Email**

zahra.valipour74@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

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Mashhad University of Medical Science, Daneshgah St.

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vcresearch@mums.ac.ir

**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

**Other areas of specialty/work**

Ear, Nose, and Throat

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Ehsan Khadivi

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Zahra Valipour

**Position**

ENT Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ear, Nose, and Throat

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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