

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Evaluation of the effect of Pillar flap posterior technique to increase the length of the palate and improve the velopharyngeal insufficiency (vpi) in patients with cleft palate with velopharyngeal insufficiency

Protocol summary

Study aim

Determining the effect of the posterior Pilar Flap technique on the improvement of hyper nasality speech in patients with cleft palate

Design

After obtaining permission from the Medical Ethics Committee of Isfahan University of Medical Sciences, after identifying patients who are candidates for surgery to resolve the VPI problem, first a written consent is obtained from the patients or their companion . Routine treatments and care and preoperative care are provided equally to all patients. The method of blinding will be that the physician who is administrator will perform the posterior pillar flap surgery , but the outcome of the operation is assessed by a skilled speech therapist who is not in the study. Only one group without randomization and one way blind without control group

Settings and conduct

patients enter the study at the time of admission to the hospital and fulfill the necessary conditions, respectively. It is a clinical trial without a control group that is performed in 1400&1401 in Al-Zahra Hospital in Isfahan

Participants/Inclusion and exclusion criteria

A patient with a hypernasality speech due to cleft palate, who is satisfied to participate in the study, and the patient's who discotinue subsequent visits to determine the state of recovery means leaving the study

Intervention groups

After being placed on the operating table, patients are subjected to cardiorespiratory monitoring and under general anesthesia, the posterior pillar flap operation is performed on them. In this technique, the posterior posterior mucosa of the flap is opened and the nasal mucosa is separated by z-plasty. The length of the palate is increased and the oral and nasal mucosa are repaired as a duct. Postoperative care is provided for all patients and in addition training the necessary care to the patient

Main outcome variables

Correct patients' speech

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220101053590N1**

Registration date: **2022-02-01, 1400/11/12**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-01, 1400/11/12**

Update count: **0**

Registration date

2022-02-01, 1400/11/12

Registrant information

Name

Azadeh sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3272 0215

Email address

sadeghiazadeh4847@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Pillar flap posterior technique to increase the length of the palate and improve the velopharyngeal insufficiency (vpi) in patients with cleft palate with velopharyngeal insufficiency

Public title
Improving the complication of nasal speech in patients with cleft palate by increasing the length of the palate with a new surgical method

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patient with nasal talk disorder due to cleft palate Do not have a lung infection and ear, nose and throat area during the operation Patient or companion consent to participate in the study
Exclusion criteria:
 Lack of subsequent patient visits to determine recovery status

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **35**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The method of blinding will be that the physician performing the posterior pyloric flap surgery is performed, but the outcome of the operation is assessed by a skilled speech therapist who is not in the study.

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical

Sciences

Street address
Isfahan University of Medical Sciences.Hezar gerib street

City
Isfahan

Province
Isfahan

Postal code
81746773461

Approval date
2021-11-22, 1400/09/01

Ethics committee reference number
IR.MUI.MED.REC.1400.646

Health conditions studied

1

Description of health condition studied

hyper nasal speech in cleft palate

ICD-10 code

Q00-Q99

ICD-10 code description

Congenital malformations,defomations and chromosomal abnormalities

Primary outcomes

1

Description

Percentage of people with improved speech in the nose after surgery

Timepoint

6 months and one year after surgery

Method of measurement

Nasoendoscopy and fluoroscopy and speech therapy

Secondary outcomes

1

Description

Vpi intensity

Timepoint

6 months and one year after surgery

Method of measurement

Nasoendoscopy and fluroscopy

Intervention groups

1

Description

Intervention group: Fluoroscopy, nasovandoscopy, and preoperative and postoperative speech therapy, as well as post-operative bed rest, are monitored by cardiorespirators, and under general anesthesia, the posterior pillar-flap operation is performed on them. In this technique, the posterior posterior mucosa of the flap

is opened and the nasal mucosa is separated by z-plasty. The length of the palate is increased and the oral and nasal mucosa are repaired as a duct.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra hospital

Full name of responsible person

Azadeh sadeghi

Street address

Al-Zahra Educational and Medical Center.Soffe Blvd

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<http://alzahra.mui.ac.ir>

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

Esfahan University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research and Technology, Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences and Health Services.Hezar Jarib St.

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Web page address

<http://www.mui.ac.ir>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Azadeh Sadeghi

Position

Plastic Surgery Resident

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

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

Esfahan University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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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