

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effect of "Lateral Crural Overlay" with "Lateral Crural Strut Graft with Transposition technique" on Cephalic Malposition in septorhinoplasty

Protocol summary

Study aim

Comparing the effect of "Lateral Crural Overlay" with "Lateral Crural Strut Graft with Transposition technique" on Cephalic Malposition in septorhinoplasty

Design

Two arm parallel group, double-blinded, randomized clinical trial

Settings and conduct

The current study will be conducted in Alzahra Hospital affiliated to Isfahan University of Medical Sciences. The patients with cephalic malposition who are candidate for septorhinoplasty surgery will be block-randomized to the surgical treatment of either lateral crural overlay or Lateral Crural Strut Graft with Transposition technique, and the surgical outcomes will be compared. The patients and the statistician will be blinded to the type of surgery.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1) 18-year-old patients and older, 2) Lateral Crural Cephalic Malposition in primary septorhinoplasty candidates
Unmet Criteria: 1) Prior history of septoplasty or rhinoplasty 2) Sinonasal Pathology: Chronic Sinusitis, Nasal Polyposis, Asthma, Allergic Rhinitis

Intervention groups

"Lateral Crural Overlay" Group: The lateral crura is incised with the proportion of one-third lateral and two-third medial. Vestibular skin is elevated and the cut cartilage is placed caudally from the anterior part in normal anatomical position, and then will be sutured.
"Lateral Crural Strut Graft with transposition technique" group: The most lateral part of the lateral crura is divided into two parts vertically. Then, the vestibular skin is elevated from the lateral to the medial part of the lateral crura. A subcutaneous pocket is placed in a caudal position between accessory cartilage and alar groove. Eventually, the freed lateral crura will be inserted into

new created cephalic packets, and the skin will become intact.

Main outcome variables

Lateral Crural Angle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190801044401N1**

Registration date: **2019-12-29, 1398/10/08**

Registration timing: **retrospective**

Last update: **2019-12-29, 1398/10/08**

Update count: **0**

Registration date

2019-12-29, 1398/10/08

Registrant information

Name

Hossein Ghazavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2020

Email address

h.ghazavi@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2020-06-05, 1399/03/16

Actual recruitment start date

2018-07-23, 1397/05/01
Actual recruitment end date
2019-09-06, 1398/06/15
Trial completion date
2019-09-11, 1398/06/20

Scientific title

Comparing the effect of "Lateral Crural Overlay" with "Lateral Crural Strut Graft with Transposition technique" on Cephalic Malposition in septorhinoplasty

Public title

Comparing the effect of two different techniques on Cephalic Malposition in septorhinoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

"Lateral Crural Cephalic Malposition" in primary septorhinoplasty candidates 18-year-old patients and older

Exclusion criteria:

Prior history of septoplasty Sinonasal Pathology: Chronic Sinusitis, Nasal Polyposis, Asthma, Allergic Rhinitis Prior history of rhinoplasty

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **45**

Actual sample size reached: **38**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization took place in the operation room by opening a numbered envelope. The envelopes were prepared by the trial statistician by using the block randomization method (block size of 4). Investigators and individuals who analyzed the outcomes were unaware of the randomization schedule.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients were unaware of the method of surgery as the randomization was performed in operation room. Besides, the statistician received the encoded information, therefore, he was unaware of each of the codes.

Placebo

Not used

Assignment

Parallel

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

Hezarjarib Ave.

City

Isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2017-10-28, 1396/08/06

Ethics committee reference number

IR.MUI.REC.1396.3.458

Health conditions studied

1

Description of health condition studied

Lateral Crural Cephalic Malposition in primary Septorhinoplasty Candidates

ICD-10 code

J34.2

ICD-10 code description

Deviated nasal septum

Primary outcomes

1

Description

Lateral Crural Angle: the angle between longitudinal lateral crural axis and midline

Timepoint

Preoperation and one year postoperation

Method of measurement

Protractor

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Cephalic Malposition will be corrected by "Lateral Crural Overlay" technique

Category

Treatment - Surgery

2

Description

Intervention group: Cephalic Malposition will be corrected by "Lateral Crural Strut Graft with Transposition technique" with transposition technique.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Hossein Ghazavi

Street address

Soffeh Blvd.

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8174675731

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Email

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Web page address

http://alzahra.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mojgan Mortazavi

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mortazavi@med.mui.ac.ir

Web page address

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

Hossein Ghazavi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data include the patients' demographic information and data related to cephalic malposition that may be accessible only by the permission of the responsible professor

When the data will become available and for how long

In the case of the professor permission, the data are accessible at any time

To whom data/document is available

Only the people can access the data that are confirmed by the professor responsible for the study

Under which criteria data/document could be used

In order to publish similar studies and by the permission of the professor responsible or the study, the data will be provided

From where data/document is obtainable

It should be contacted to the professor responsible for the study

What processes are involved for a request to access data/document

It should be contacted to the professor through call or email

Comments