Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison Between Double Lateral Osteotomy and Asymmetric Dorsal Hump Reduction in Correction of Crooked Nose

Protocol summary

Study aim

Crooked noses and very wide noses are one of the most severe forms of the nasal deformity and since many interpersonal relationships are done face-to-face daily, this deformity is very annoying for people who do not correct it irreversibly and can lead to decreased self-esteem. In this project, we investigate the effect of double lateral osteotomy on the correction of tilting of the lateral nasal walls and compare it with asymmetrical dorsal hump reduction.

Design

A double-blinded, parallel group randomised clinical trial

Settings and conduct

This study was performed in Taleghani Hospital, Tehran, Iran. After obtaining informed consent from patients, grouping them and storing information before and after intervention, data analysis was performed. Participants, health care providers, and analyzers of this study were blinded to the method used.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients with crooked nose. Exclusion criteria include patients with S-shaped deformities of the nose, patients with facial asymmetrys and patients with nasal curvature due to cartilage structures.

Intervention groups

In one group double lateral osteotomy and in the other group an asymmetrical reduction of dorsal nasal height is used to correct nasal bending.

Main outcome variables

Nasal deviation correction, evaluation of deviation correction by each method, introduce a more effective method in correction of nasal deviation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200123046232N1**
Registration date: **2020-02-22, 1398/12/03**
Registration timing: **retrospective**

Last update: **2020-02-22, 1398/12/03**
Update count: **0**

Registration date

2020-02-22, 1398/12/03

Registrant information

Name

Sara Nouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2267 6231

Email address

nourisara@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Between Double Lateral Osteotomy and Asymmetric Dorsal Hump Reduction in Correction of Crooked Nose

Public title

Correction of Crooked Nose

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with Crooked Nose

Exclusion criteria:

S Shape Deformity of Nose Facial Asymmetry Cartilage Deformity

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method using random number tables. The randomization unit is individual. Allocation concealment through sealed opaque envelopes with random sequences.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants in this study, clinical caregivers, outcome assessors, and data analysts were kept blind to the procedure performed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

No. 1, Shirin Dd End, North Mehrmohammadi St, Qeitarieh Blvd.

City

Tehran

Province

Tehran

Postal code

1934965131

Approval date

2019-08-05, 1398/05/14

Ethics committee reference number

IR.SBMU.MSP.REC.1398.427

Health conditions studied

1

Description of health condition studied

Crooked nose

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Measurement of difference in degree of nasal deviation before and after surgery

Timepoint

Baseline (before intervention), 6 and 12 months after surgery

Method of measurement

Degree of nasal deviation using patient's photography

Secondary outcomes

1

Description

Patient satisfaction

Timepoint

12 months after surgery

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Patients undergoing double lateral osteotomy.

Category

Treatment - Surgery

2

Description

Intervention group: Patients undergoing asymmetrical dorsal hump reduction

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani Hospital

Full name of responsible person
Ali Goljanian Tabrizi

Street address
Taleghani Educational Hospital, Shahid Erabi St., Daneshjou Blvd., Velenjak Region, Chamran High Way

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taleghanihospital@sbmu.ac.ir

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http://taleghani.sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

Street address
Taleghani Educational Hospital, Shahid Erabi St., Daneshjou Blvd., Velenjak Region, Chamran High Way

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zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Sara Nouri

Position
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)
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
All potential data of participants is shared after being unidentified.

When the data will become available and for how long
Start of access period 12 months after releasing the results.

To whom data/document is available
It will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
In order to use the data to compare them with data of similar studies

From where data/document is obtainable
nourisara@sbmu.ac.ir

What processes are involved for a request to access data/document
After receiving the request and reviewing the applicant's information and ensuring that it is correct, within 1-2 weeks the information will be available to the applicant.

Comments