

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The Comparative Study on Outcome of septoplasty with and without unilateral Pyriform Turbinoplasty on concave side of septum in patients with septal deviation treated

Protocol summary

Study aim

Evaluation of both septoplasty alone and septoplasty with resect preform aperture in concave part and selecting a more suitable method for patients with nasal obstruction

Design

The study is performed in a double blind method with randomization. The studied groups are two groups of case and control. The number of samples is statistically estimated to be 60 people who are divided into 2 parallel groups of 30 people and are randomly intervened

Settings and conduct

This study is a double-blind clinical trial in patients with nasal deviation referred to Taleghani Hospital. Septoplasty is performed for all patients, but for some patients it is performed as a random septoplasty with one-sided turbinoplasty preform on the concave side

Participants/Inclusion and exclusion criteria

Admission: Patients over 18 years of age with a diagnosis of nasal deviation who need septoplasty based on history and examination without surgery and without underlying disease: diabetes, thyroid disorders, asthma, polyposis, vasculitis and rheumatic diseases Exit: no follow-up - characterized by associated disease

Intervention groups

Patients over 18 years of age with a diagnosis of nasal deviation who require septoplasty based on history and examination and undergo septoplasty and preform aperture resection. In the control group, only septoplasty surgery is performed

Main outcome variables

In this study headache; Age; sex; nasal congestion; airflow; degree of nasal deviation; duration of nasal obstruction; A history of allergic rhinitis is examined

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210218050403N1**

Registration date: **2021-11-20, 1400/08/29**

Registration timing: **prospective**

Last update: **2021-11-20, 1400/08/29**

Update count: **0**

Registration date

2021-11-20, 1400/08/29

Registrant information

Name

Homeira Mansurzade roodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5422 5359

Email address

mansurzade.homeira@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-10, 1400/09/19

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparative Study on Outcome of septoplasty with and without unilateral Piriform Turbinoplasty on concave side of septum in patients with septal deviation treated

Public title

The Comparative Study on Outcome of septoplasty with and without unilateral Piriform Turbinoplasty on concave side of septum in patients with septal deviation treated

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient over 18 years old need Septoplasty : septal deviation Diagnosed according to History and Examination Without prior Septoplasty surgery Without comorbidity such as : Diabetes mellitus. Thyroid disorder. Asthma. Polyposis . Tomato logic and Vasculitis Disorder

Exclusion criteria:

Miss follow up Diagnosed Comorbidity

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization : 4 groups divided into A to C that were randomly selected from each group that septoplasty is performed randomly with concave turbinoplasty intervention or septoplasty alone. Finally in 60 samples; 30 septoplasty alone and 30 septoplasty and perform Convex turbinoplasty is performed

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients know they need Septoplasty with or without piriform aperture Turbinoplasty. The surgeon describes every kind of surgery. At the end patients and researcher don't know which one done for them.

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

Headquarters of the Ministry of Health, No.13, Block A, Between South Flamek and Zarafshan, QodsTown, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2020-12-28, 1399/10/08

Ethics committee reference number

IR.SBMU.MSP.REC.1399.546

Health conditions studied

1

Description of health condition studied

Septal Deviation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Nasal obstruction is the main variable of the study and 60 samples are needed to evaluate the effect of the intervention

Timepoint

Nasal obstruction is examined before the intervention and 2 months and 6 months after surgery

Method of measurement

It is examined by rhinomanometric device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients undergoing septoplasty surgery with piriform aperture resect.

Category

Treatment - Surgery

2

Description

Control group: Patients undergoing only septoplasty .

Category

Treatment - Surgery

Country of origin**Type of organization providing the funding**

Academic

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

Taleghani Hospital

Full name of responsible person

Homeira Mansourzadeh Rudi

Street address

erabi

City

Tehran

Province

Tehran

Postal code

363633636

Phone

+98 21 4486 3960

Email

mansurzade.homeira@gmail.com

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Ziaei

Street address

Unit 6, Darkeh, Arman Building, No. 42, Ahmadpour Street; Darakeh

City

Tehran

Province

Tehran

Postal code

1984100000

Phone

+98 21 2241 4024

Email

mansurzade.homeira@gmail.com

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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Homeira mansurzade rudi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Unit 6, Arman Building, No. 42, Ahmadpour Street, Darkeh

City

Tehran

Province

Tehran

Postal code

1984100000

Phone

+98 21 2241 4024

Email

mansurzade.homeira@gmail.com

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Homeira mansurzade rudi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Unit 6, Arman Building, No. 42, Ahmadpour Street; Darkeh

City

Tehran

Province

Tehran

Postal code

1984100000

Phone

+98 21 2241 4024

Email

mansurzade.homeira@gmail.com

Person responsible for updating data**Contact**

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Homeira mansurzade rudi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Unit 6, Arman Building, No. 42, Ahmadvour Street,
Darkeh

City

Tehran

Province

Tehran

Postal code

1984100000

Phone

+98 21 2241 4024

Email

mansurzade.homeira@gmail.com

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

Manometric data and patients' questionnaires can be shared after being unidentified

When the data will become available and for how long

3 months after printing the results

To whom data/document is available

Researchers in academic institutions

Under which criteria data/document could be used

The data obtained from the questionnaire and manometry can be presented for further studies

From where data/document is obtainable

Applicants should send a request letter to the researcher's email to access the data.
mansurzade.homeira@gmail.com

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

The applicant will apply to the mentioned e-mail by introducing himself / herself and the relevant university and the published data will be provided within two weeks

Comments