Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Pyriform 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 Pyriform Turbinoplasty on concave side of septum in patients with septal deviation treated

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pation over 18 years old need Septoplasty : septal deviation Diagnosed according to History and Examination Without perior Septoplasty surgery Without comorbidity such as : Diabetes mellitus. Thyroid disorder. Asthma. Polyposis . Tomato logic and Vasculitis Didorder

Exclusion criteria:
Miss fallow 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 preform Convex turbinoplasty is performed

Blinding (investigator's opinion)
Double blinded

Blinding description
Pations know they need Septoplasty with or without priform aperture Turbinoplasty. The surgeon describe every kind of surgery.At the End pations 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 septplasty surgery with priform aperture resect.

Category
Treatment - Surgery

2

Description
Control group: Patients undergoing only septoplasty .

Category
Treatment - Surgery

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
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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
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
Homeira mansurzade rudi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
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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
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