Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Aesthetic and Functional Outcomes of Dorsal Preservation Rhinoplasty In Comparison With Dorsal Resection Technique in Rhinoplastic Surgery Candidates

Protocol summary

Study aim

Evaluation of aesthetic and functional outcomes of dorsal preservation rhinoplasty in comparison with dorsal resection technique in rhinoplastic surgery candidates referred to Otolaryngology clinic of Imam Khomeini hospital complex

Design

In two parallel groups(dorsal resection and dorsal preservation), a randomized trial, single-blinded and randomized in blocked randomization method, on 100 patient(50 in each groups)

Settings and conduct

This study will be performed in the convenience sampling method. Patients will be divided into dorsal resection and dorsal preservation groups, using randomized and single-blinded methods, so that participants will not know the method used in the surgery. The randomization method is the blocked randomization method

Participants/Inclusion and exclusion criteria

All the patients who get referred to the plastic surgery clinic of Imam Hospital, from 1400 to 1401, and become candidates for rhinoplasty surgery, if are willing to, can get included in the study. Meanwhile, those who it's not their first time getting rhinoplasty surgery, or have a history of previous systemic diseases, and also, those with severe nasal deviation, nasal septum, broad nose, kyphotic bone hump, and k point on the bony area, will be excluded from the trial.

Intervention groups

Patients in the dorsal preservation group will be operated through the middle strip method and for those in the dorsal resection group it will be through the spreader flap.

Main outcome variables

Satisfaction with the result of the surgery; VAS score; SCHNOS score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080820001056N7**
Registration date: **2022-11-15, 1401/08/24**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-15, 1401/08/24**
Update count: **0**

Registration date

2022-11-15, 1401/08/24

Registrant information

Name

babak saedi

Name of organization / entity

tehran university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 21 2270 0765

Email address

saedi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-10, 1401/03/20

Expected recruitment end date

2023-06-10, 1402/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of Aesthetic and Functional Outcomes of Dorsal Preservation Rhinoplasty In Comparison With Dorsal Resection Technique in Rhinoplastic Surgery Candidates

Public title
Evaluation of aesthetic and functional outcomes of two different types of rhinoplasty surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All the patients who get referred to the plastic surgery clinic of Imam Hospital, from the year 1401 to 1402, and become candidates for rhinoplasty surgery.
Exclusion criteria:
Those who it's not their first time getting rhinoplasty surgery. Those with a history of previous systemic diseases. Those with severe nasal deviation. Those with the nasal septum. Those who have a wide nose. Those with kyphotic bone hump. If K point is placed on the bony area.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients with Block randomization method are grouped into quadruple blocks, designed by a statistical methodologist. we used Random allocation software to create to create random sequence plus simple randomization in block randomization method.The random assignment list is at the disposal of the supervisor and based on that, patients who have been given surgery and are satisfied with the surgery are divided into groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
As it is not possible to blind the surgeon, only the participants will not know the method used in the surgery. Data collectors and those evaluating the outcome, as well as the Data Safety and Monitoring Committee and those drafting the article, are also blinded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Imam Khomeini Hospital -Tehran University of Medical Sciences
Street address
Central building of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.
City
tehran
Province
Tehran
Postal code
1419733141
Approval date
2021-05-19, 1400/02/29
Ethics committee reference number
IR.TUMS.IKHC.REC.1400.065

Health conditions studied

1

Description of health condition studied
Rhinoplasty
ICD-10 code
M95.0
ICD-10 code description
Acquired deformity of nose

Primary outcomes

1

Description
Patient satisfaction with the result
Timepoint
One month before the intervention and then a year after the surgery
Method of measurement
based on the patient’s evaluation by Visual Analogue Scale(1-10)

2

Description
Respiratory function
Timepoint
One month before the intervention and then a year after the surgery
Method of measurement
SCHNOS(Standardized Cosmesis and Health Nasal Outcome Survey)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the dorsal preservation group, who will be operated through the middle strip method. Preservation rhinoplasty refers to several components of rhinoplasty, including (1) elevating the nasal soft tissue in a subperichondrial–subperiosteal plane, (2) limited excision of alar cartilages, and (3) maintaining the osseocartila- ginous dorsum without violation of the bony–cartilaginous interface.
Category
Treatment - Surgery

2

Description
Intervention group: Patients in the dorsal resection group who will be operated through the spreader flap. the surgeon makes a small Z-shaped incision between the nostrils on the underside of the nose
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Otolaryngology Clinic of Imam Khomeini Hospital Complex
Full name of responsible person
Dr. Babak Saedi
Street address
Qarib St., Keshavarz Blvd
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Tehran
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Email
Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraian
Street address
Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.
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Phone
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tumspr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Rojan Zarei
Position
Researche
Latest degree
Medical doctor
Other areas of specialty/work
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Professor
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Subspecialist
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Person responsible for updating data

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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 data is potentially shareable after unidentified individuals
When the data will become available and for how long
Six months after publication
To whom data/document is available
Researchers
Under which criteria data/document could be used
Only for researching purposes
From where data/document is obtainable
Rojan Zarei email: Zareirojan93@gmail.com
What processes are involved for a request to access data/document
A written request from a valid place is required. Then, within 2 weeks the data will be provided.
Comments