

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jul 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                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Scientific title</b>                       | Evaluation of Aesthetic and Functional Outcomes of Dorsal Preservation Rhinoplasty In Comparison With Dorsal Resection Technique in Rhinoplastic Surgery Candidates                                                                                                                                                                                                                                                                     |
| <b>Public title</b>                           | Evaluation of aesthetic and functional outcomes of two different types of rhinoplasty surgery                                                                                                                                                                                                                                                                                                                                           |
| <b>Purpose</b>                                | Supportive                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Inclusion/Exclusion criteria</b>           |                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Inclusion criteria:</b>                    | 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.                                                                                                                                                                                                                                                                            |
| <b>Exclusion criteria:</b>                    | 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.                                                                                                                                                  |
| <b>Age</b>                                    | From <b>18 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Gender</b>                                 | Both                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Phase</b>                                  | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Groups that have been masked</b>           | <ul style="list-style-type: none"> <li>Participant</li> </ul>                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Sample size</b>                            | Target sample size: <b>50</b>                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Randomization (investigator's opinion)</b> | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Randomization description</b>              | 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. |
| <b>Blinding (investigator's opinion)</b>      | Single blinded                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Blinding description</b>                   | 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.                                                                                                                                                                 |
| <b>Placebo</b>                                | Not used                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Assignment</b>                             | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Other design features</b>                  |                                                                                                                                                                                                                                                                                                                                                                                                                                         |

|                                                |                                                                                      |
|------------------------------------------------|--------------------------------------------------------------------------------------|
| <b>Secondary Ids</b>                           | empty                                                                                |
| <b>Ethics committees</b>                       |                                                                                      |
| <b>1</b>                                       |                                                                                      |
| <b>Ethics committee</b>                        |                                                                                      |
| <b>Name of ethics committee</b>                | Ethics committee of Imam Khomeini Hospital -Tehran University of Medical Sciences    |
| <b>Street address</b>                          | Central building of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd. |
| <b>City</b>                                    | tehran                                                                               |
| <b>Province</b>                                | Tehran                                                                               |
| <b>Postal code</b>                             | 1419733141                                                                           |
| <b>Approval date</b>                           | 2021-05-19, 1400/02/29                                                               |
| <b>Ethics committee reference number</b>       | IR.TUMS.IKHC.REC.1400.065                                                            |
| <b>Health conditions studied</b>               |                                                                                      |
| <b>1</b>                                       |                                                                                      |
| <b>Description of health condition studied</b> | Rhinoplasty                                                                          |
| <b>ICD-10 code</b>                             | M95.0                                                                                |
| <b>ICD-10 code description</b>                 | Acquired deformity of nose                                                           |
| <b>Primary outcomes</b>                        |                                                                                      |
| <b>1</b>                                       |                                                                                      |
| <b>Description</b>                             | Patient satisfaction with the result                                                 |
| <b>Timepoint</b>                               | One month before the intervention and then a year after the surgery                  |
| <b>Method of measurement</b>                   | based on the patient's evaluation by Visual Analogue Scale(1-10)                     |
| <b>2</b>                                       |                                                                                      |
| <b>Description</b>                             | Respiratory function                                                                 |
| <b>Timepoint</b>                               | One month before the intervention and then a year after the surgery                  |
| <b>Method of measurement</b>                   | 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 osseocartilaginous 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

##### City

tehran

##### Province

Tehran

##### Postal code

1419733141

##### Phone

+98 21 6119 0000

##### 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.

#### City

tehran

#### Province

Tehran

#### Postal code

1417653911

#### Phone

+98 21 6405 3334

#### Email

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

Researcher

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Ear, Nose, and Throat

##### Street address

Qarib St., Keshavarz Blvd

##### City

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##### Province

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##### Postal code

1419733141

##### Phone

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##### Email

Zareirojan93@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Dr. Babal Saedi  
**Position**  
Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Rojan Zarei  
**Position**  
Researcher  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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**Phone**  
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**Email**  
Zareirojan93@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

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