

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of the amount of bony and cartilaginous hump removal on final dorsal aesthetic line after rhinoplasty

Protocol summary

Study aim

The aim of this study is to evaluate the effect of cartilaginous and bony hump removal on final aesthetic dorsal line after rhinoplasty.

Design

40 patients with nasal deformity attending Ear, Nose & Throat clinic of Imam Khomeini hospital that fulfill the inclusion criteria will be selected for this study.

Settings and conduct

This study is conducted in the ENT department of Imam Khomeini hospital. All eligible candidates are asked to complete 2 questionnaires (demographic and NOSE), preoperative and postoperative standard photography are analyzed with Image J program to evaluate the effect of estimated hump removal and intra-operative hump removal with the final dorsal aesthetic line and patients satisfaction based on ROE questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients at the age of 18 years old or higher with normal psychological background who can pay the surgical expenses are included. Exclusion criteria: previous history of septoplasty or septorhinoplasty; severe deviated nose; craniofacial anomalies; cleft lip nose; severe facial trauma; saddle nose; pregnancy; immunodeficiency and follow-up duration less than 6 months

Intervention groups

The main intervention is hump (cartilaginous and bony) removal in septorhinoplasty.

Main outcome variables

The main outcome of this study are patient's satisfaction and final nasal dorsal aesthetic line according to aesthetics assessments.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170130032287N2**

Registration date: **2018-01-17, 1396/10/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-17, 1396/10/27**

Update count: **0**

Registration date

2018-01-17, 1396/10/27

Registrant information

Name

Amir Arvin Sazgar

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1628

Email address

asazgar@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Science

Expected recruitment start date

2017-05-22, 1396/03/01

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

The effect of the amount of bony and cartilaginous hump removal on final dorsal aesthetic line after rhinoplasty

Public title

The effect of hump and bony reduction on final dorsal aesthetic line

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients with the age of 18 or more being mentally healthy (according to the questionnaire) Financial ability to afford the cost of surgery

Exclusion criteria:

History of Septoplasty or septorhinoplasty Severe deviated nose Craniofacial anomalies Cleft lip nose History of severe traumas which have caused serious anatomical changes Saddle nose Pregnancy Immunodeficiency Duration of follow-up less than 6 months

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Central department of Tehran University of Medical Sciences, Intersection of Keshavarz blvd. and Qods St.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-05-03, 1396/02/13

Ethics committee reference number

IR.TUMS.VCR.REC.1396.2203

Health conditions studied**1****Description of health condition studied**

Acquired Nasal deformity

ICD-10 code

J34.2

ICD-10 code description

Deviated nasal septum

2**Description of health condition studied**

congenital nose deformity

ICD-10 code

Q30.9

ICD-10 code description

Congenital malformation of nose, unspecified

Primary outcomes**1****Description**

Final nasal dorsal aesthetic line.

Timepoint

first, third, sixth and 12th months

Method of measurement

measurement of angles and distances of the face on standard photographs using Image J software

Secondary outcomes**1****Description**

Patient's satisfaction of final result of rhinoplasty surgery

Timepoint

At the end of the trial

Method of measurement

ROE (Rhinoplasty Outcomes Evaluation) questionnaire

Intervention groups**1****Description**

Patients will undergo septorhinoplasty with open approach. The bony and cartilaginous hump are removed separately after degloving of the skin and separation of bilateral upper lateral cartilages. The removed bony and cartilaginous parts are measured exactly.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Dr. Narges Mikaniki

Street address

Valiasr Hospital, Imam Khomeini Hospital Complex,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of
Medical Science

Full name of responsible person

Dr. Ali Sahraian

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Sciences, Intersection of Keshavarz blvd. and Qods St.

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical
Science

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

Dr Narges Mikaniki

Position

Resident of Otolaryngology

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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Tehran University of Medical Sciences

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Otolaryngologists

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Amir Arvin Sazgar

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Professor

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Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

According to the written consent signed by the participants all data are confidential and not to be shared with others.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available