Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of complications of septoplasty with and without nasal splint

Protocol summary

Summary

in this clinical trial study with the intention to treat goal, 48 candidates of septoplasty surgery that hospitalized in Tabriz Imam Reza hospital in the first half of 2017 will enroll. all enrolled patients will fill the informed contest. The necessary measures for illiterate patients are also considered. patients will divide into experimental and control groups and will match in terms of age, sex and severity of the disease. Suturing will be used in the intervention group instead of nasal splint that will be used in the control group as routine surgical procedures. The two groups will comparison in terms of postoperative pain, hematoma formation, septum perforation or nasal obstruction after 2 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021832645N1**
Registration date: **2017-03-01, 1395/12/11**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-03-01, 1395/12/11

Registrant information

Name

Shahram Gasembaglou

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

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+98 33355921

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Recruitment status

Recruitment complete

Funding source

All financial costs arising from this study is the responsibility of the researcher

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of complications of septoplasty with and without nasal splint

Public title

Evaluating the need of nasal splint in septoplasty surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion: 1-consent to participate in the study 2-septoplasty candidates exclusion: 1-Lack of consent to participate in the study 2-Patients which need additional surgeries while undergoing septoplasty surgery 3-Patients that won't cooperate during follow-up period

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of medical sciences
Street address
Daneshgah St., Tabriz University of medical sciences
City
Tabriz
Postal code
Approval date
2017-01-28, 1395/11/09
Ethics committee reference number
ir.tbz.med.rec.1395.11.28

Health conditions studied

1

Description of health condition studied
septoplasty
ICD-10 code
J34.2
ICD-10 code description
Deflection or deviation of septum (nasal)(acquired)

Primary outcomes

1

Description
Complications
Timepoint
2 weeks after intervention
Method of measurement
clinical examination

Secondary outcomes

1

Description
pain severity assessmnet
Timepoint
2 weeks after intervention
Method of measurement
visual pain scale

Intervention groups

1

Description
intervention: Not using splint after septoplasty
Category
Treatment - Surgery

2

Description
control: using splint after septoplasty
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Imam Reza hospital
Full name of responsible person
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz university of medical sciences
Full name of responsible person
research deputy of Tabriz university of medical sciences
Street address
Daneshgah st., Tabriz university of medical sciences
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of medical sciences

Full name of responsible person

Reza Bahman

Position

medical student

Other areas of specialty/work

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nezami st, aftab tower

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Shahram Gasembaglou

Position

proffessor- medical specialty degree in ENT

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty