

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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)

##### Phone

+98 33355921

##### Email address

ghasembaglou@tbzmed.ac.ir

##### 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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mr\_bahman@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Shahram Gasembaglou

**Position**

professor- medical specialty degree in ENT

**Other areas of specialty/work**

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## 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*