

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of septoplasty with and without nasal packing on the complications and outcomes of surgery in patients who are candidate for septoplasty: a randomized clinical trial

#### Protocol summary

##### Study aim

To compare septoplasty with and without nasal packing on the complications and outcomes of surgery in patients who are candidate for septoplasty

##### Design

This is a randomized clinical trial, in which 56 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible patients who are candidate for septoplasty and will refer to Besat Hospital during the study period will be enrolled in the trial

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years; Candidate for septoplasty Exclusion criteria: Incidence of trauma after surgery; A history of nasal granulomatosis; Need for turbinate surgery

##### Intervention groups

Intervention group: Septoplasty with nasal packing including a narrow and long dressing bandage smeared with tetracycline ointment Control group: Septoplasty without nasal packing including

##### Main outcome variables

Primary outcome: Measuring pain Measuring anxiety Assessing the quality of breathing and sleep Secondary outcome: Measuring the severity of bleeding and leakage Measuring the septal hematoma

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N243**

Registration date: **2018-10-17, 1397/07/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-10-17, 1397/07/25**

Update count: **0**

##### Registration date

2018-10-17, 1397/07/25

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-05-22, 1397/03/01

##### Expected recruitment end date

2018-11-22, 1397/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of septoplasty with and without nasal packing on the complications and outcomes of surgery in patients who are candidate for septoplasty: a randomized clinical trial

##### Public title

Comparison of septoplasty with and without nasal packing on the complications and outcomes of surgery in patients who are candidate for septoplasty

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Age of 18 to 65 years; Candidate for septoplasty

##### **Exclusion criteria:**

Incidence of trauma after surgery; A history of nasal granulomatosis; Need for turbinate surgery

#### **Age**

From **18 years** old to **65 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **56**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

The patients will be randomly assigned to intervention and control groups using block randomization

#### **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 Hamadan University of Medical Sciences

###### **Street address**

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

###### **City**

Hamadan

###### **Province**

Hamadan

###### **Postal code**

6517838695

##### **Approval date**

2018-05-19, 1397/02/29

##### **Ethics committee reference number**

IR.UMSHA.REC.1397.91

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Pain

##### **ICD-10 code**

G89.18

##### **ICD-10 code description**

Other acute postprocedural pain

#### **2**

##### **Description of health condition studied**

Anxiety

##### **ICD-10 code**

F41.9

##### **ICD-10 code description**

Anxiety disorder, unspecified

### **Primary outcomes**

#### **1**

##### **Description**

Measuring pain

##### **Timepoint**

24 hours, one week, and 3 months after surgery

##### **Method of measurement**

Using Visual Analog Scale (VAS)

#### **2**

##### **Description**

Measuring anxiety

##### **Timepoint**

24 hours, one week, and 3 months after surgery

##### **Method of measurement**

Using standard questionnaire

#### **3**

##### **Description**

Assessing quality of breathing and sleep

##### **Timepoint**

24 hours, one week, and 3 months after surgery

##### **Method of measurement**

Through history taking

### **Secondary outcomes**

#### **1**

##### **Description**

Measuring the severity of bleeding and leakage

##### **Timepoint**

24 hours and one week after surgery

##### **Method of measurement**

Through physical examination

## 2

### Description

Measuring the septal hematoma

### Timepoint

24 hours and one week after surgery

### Method of measurement

Through physical examination

## Intervention groups

### 1

#### Description

Intervention group: Septoplasty with nasal packing including a narrow and long dressing bandage smeared with tetracycline ointment

#### Category

Treatment - Surgery

### 2

#### Description

Control group: Septoplasty without nasal packing including

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat Hospital

##### Full name of responsible person

Dr Sahar Yousefnejad

##### Street address

Besat Hospital, Shahed Square

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6517838695

##### Phone

+98 81 3364 0030

##### Email

Sahar.yousefnejad@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr Saeid Bashirian

##### Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

#### City

Hamadan

#### Province

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#### Postal code

6517838695

#### Phone

+98 81 3838 0717

#### Email

info.research@umsha.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr Sahar Yousefnejad

##### Position

Resident of ENT

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Ear, Nose, and Throat

##### Street address

Besat Hospital, Shahed Square

##### City

Hamadan

##### Province

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr Elnaz Shariatpanahi

**Position**

ENT Specialist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ear, Nose, and Throat

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

School of Public Health, Hamadan University of

Medical Sciences, Shahid Fahmideh Ave

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**Email**

poorolajal@umsha.ac.ir

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

Undecided - It is not yet known if there will be 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**

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

**Data Dictionary**

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