

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)

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+98 81 1838 0090

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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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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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

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

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Person responsible for scientific inquiries

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ENT Specialist

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Person responsible for updating data

Contact

Name of organization / entity

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Position

Professor of Epidemiology

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Ph.D.

Other areas of specialty/work

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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