Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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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

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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

Usng 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
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Sponsors / Funding sources

1

Sponsor
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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
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Person responsible for updating data

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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