

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative Study Septorhinoplasty With and Without Nasal Packing in Operated patients

Protocol summary

Summary

The purpose of this study was to compare the results of septorhinoplasty surgery in patients with and without tampon. This is a prospective clinical trial in patients undergoing septorhinoplasty in 2015 at Amiralmomenin Hospital. Seventy Subjects with the age range of 18-50 years of both sexes were included in the study. Exclusion criteria of our study are patients with underlying disease (such as diabetes, heart problems, high blood pressure, and blood dyscrasia), a history of nasal polyps, drug abuse, nasal allergy, blood-thinning drugs such as aspirin. Patients with a history of nasal septum and turbinate surgery, curved nasal deformity, perforated septum, saddle-shaped deformity excluded. Informed consent of the patients will be taken. The patients will be divided into two groups of with and without tampon. 35 patients underwent septorhinoplasty with packing in Time Period 1 and 35 patients underwent septorhinoplasty without packing in Time Period 2. Each Time Period is one Month. During septum surgery, both groups will be sewn with yarn 3 0 vicryl. Suture running will be performed by the surgeon. Mesh treated with tetracycline will be administered in the tampon-using group. Tampons will be removed after 48 hours. Related outcomes in the short term, medium term and long term in both groups will be checked.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507051138N21**

Registration date: **2015-08-21, 1394/05/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-21, 1394/05/30

Registrant information

Name

Fataneh Bakhshi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1223 8307

Email address

entrc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Science, Vice Chancellor for Research

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study Septorhinoplasty With and Without Nasal Packing in Operated patients

Public title

Septorhinoplasty With and Without Nasal Packing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 18-50 years; exclusion criteria: patients with underlying disease (such as diabetes, heart

problems, high blood pressure, and blood dyscrasia); a history of nasal polyps; drug abuse; nasal allergy; blood-thinning drugs such as aspirin; Patients with a history of nasal septum and turbinate surgery; nasal deformity curved; perforated septum; saddle-shaped deformity;

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Tehran avenue

City

Rasht

Postal code

Approval date

2015-06-23, 1394/04/02

Ethics committee reference number

IR.GUMS.REC.1394.78

Health conditions studied

1

Description of health condition studied

Septorhinoplasty

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Ecchymosis

Timepoint

Two days after surgery

Method of measurement

Based on clinical examination

2

Description

Bleeding

Timepoint

Two days after surgery,One week after surgery,One Month after surgery

Method of measurement

Based on clinical examination

3

Description

Patient satisfaction

Timepoint

Two days after surgery,One week after surgery,One Month after surgery

Method of measurement

Based on clinical examination

4

Description

Edema

Timepoint

Two days after surgery

Method of measurement

Based on clinical examination

5

Description

Hematoma

Timepoint

Two days after surgery

Method of measurement

Based on clinical examination

6

Description

Mucosal lesions

Timepoint

One week after surgery

Method of measurement

Based on clinical examination

7

Description

Difficulty breathing

Timepoint

One week after surgery
Method of measurement
Based on clinical examination

8

Description

Pain

Timepoint

, One week after surgery

Method of measurement

Based on clinical examination

9

Description

Secondary infection

Timepoint

One week after surgery, One Month after surgery

Method of measurement

Based on clinical examination

10

Description

Granuloma

Timepoint

One week after surgery

Method of measurement

Based on clinical examination

11

Description

Mucosal Adhesion in Nasal Airway

Timepoint

One Month after surgery

Method of measurement

Based on clinical examination

12

Description

Nasal valve stenosis

Timepoint

One week after surgery

Method of measurement

Based on clinical examination

13

Description

Marginal incision site

Timepoint

One Month after surgery

Method of measurement

Based on clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

35 patients underwent septorhinoplasty with packing in Time Period 1, septum will be sewn with yarn 3 0 vicryl. Suture running will be performed by the surgeon. Mesh treated with tetracycline will be administrated in the tampon-using group. Tampons will be removed after 48 hours.

Category

Treatment - Surgery

2

Description

35 patients underwent septorhinoplasty without packing in Time Period 2, Each Time Period is one Month. During septum surgery, septum will be sewn with yarn 3 0 vicryl. Suture running will be performed by the surgeon.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralamomenin Hospital

Full name of responsible person

Street address

Amiralamomenin Hospital, 17 shahrivar St

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Science, Vice Chancellor for Research

Full name of responsible person

Susan Komae

Street address

Gas Square, Rasht

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Guilan University of Medical Science, Vice Chancellor for Research

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
Guilan University of Medical Science

Full name of responsible person
Dr Ali Faghih habibi

Position
Assistant Professor

Other areas of specialty/work

Street address
Amiralamomenin Hospital, 17 shahrivar St

City
Rasht

Postal code

Phone
+98 13 3322 5242

Fax

Email
Dr.faghih.habibi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Guilan University of Medical Sciences

Full name of responsible person

Dr Ali Faghih habibi

Position

Assistant Professor

Other areas of specialty/work

Street address

Amiralamomenin Hospital, 17 shahrivar St

City

Rasht

Postal code

Phone

+98 13 3322 5242

Fax

Email

Dr.faghih.habibi@gmail.com

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