

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Internal versus External Lateral Nasal Osteotomy in Primary Open Rhinoplasty: Comparison of Outcomes and Complications

Protocol summary

Summary

(1) Objectives: The purpose of this article is to compare the outcomes and complications between external and internal lateral nasal osteotomy. (2) Design: Grade of edema and ecchymosis according to the designed model, asymmetry and step-off deformity by direct vision and presence of bony spore by touch; will be compared between the two groups. (3) Setting and conduct: 48 patients will be included in this study. The patients will be divided to two equal groups: internal osteotomy group (n=24) and external osteotomy group (n=24). Edema and ecchymosis 24 hours and 2, 7, and 10 days after surgery (according to the designed model), asymmetry and step-off deformity 1 month after surgery (with direct vision), and bony spore 1 month after surgery (with touch) will be compared between the two groups. (4) Participants including major eligibility criteria: Inclusion criteria: systematically healthy patients (ASA I & II): primary rhinoplasty patients and not revision; patients without significant problems in nasal structure such as thick skin; septal deviation; septal perforation; and trauma. Exclusion criteria: patients who do not accept to sign written informed consents; patient who do not attend for follow-up visits. (5) Intervention: For 24 patients nasal osteotomy will be performed externally and for 24 patients will be performed internally. (6) Main outcome measures (variables): edema, ecchymosis, asymmetry, step-off deformity, bony spore

General information

Acronym

not applicable

IRCT registration information

IRCT registration number: **IRCT2014040717164N1**

Registration date: **2014-04-30, 1393/02/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-30, 1393/02/10

Registrant information

Name

Payam Varedi

Name of organization / entity

Faculty of dentistry, Tehran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

payam.varedi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-01-13, 1392/10/23

Expected recruitment end date

2014-02-12, 1392/11/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Internal versus External Lateral Nasal Osteotomy in Primary Open Rhinoplasty: Comparison of Outcomes and Complications

Public title

Internal versus External Lateral Nasal Osteotomy in Primary Open Rhinoplasty: Comparison of Outcomes and

Complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: systematically healthy patients (ASA I & II); without disorders such as hypertension; diabetics; liver disease; renal disease; asthma; GI dysfunction; and without history of usage of anticoagulant drugs; anti-hypertension drugs; alcohol and smoke; patients candidate for primary rhinoplasty ; patients without significant problems in nasal structure such as thick skin; septal deviation; septal perforation and trauma.
Exclusion criteria: patients who do not accept to sign written consents form; patient who do not attend for follow-up visits.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 48

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

N/A

Secondary Ids

1

Registry name

N/A

Secondary trial Id

N/A

Registration date

empty

2

Registry name

ندارد

Secondary trial Id

ندارد

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Ghods avenue, Keshavarz bolivar, Tehran

City

Tehran

Postal code

Approval date

2014-02-12, 1392/11/23

Ethics committee reference number

9121250001

Health conditions studied

1

Description of health condition studied

Rhinoplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

asymmetry

Timepoint

1 month after surgery

Method of measurement

will be evaluated with direct vision

2

Description

step-off deformity

Timepoint

1 month after surgery

Method of measurement

will be evaluated with direct vision

3

Description

bony spore

Timepoint

1 month after surgery

Method of measurement

will be evaluated with touch

4

Description

edema

Timepoint

24 hours and 2, 7, and 10 days after surgery

Method of measurement

according to the designed model, which is available in the questionnaire

5

Description

ecchymosis

Timepoint

24 hours and 2, 7, and 10 days after surgery

Method of measurement

according to the designed model, which is available in the questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In external osteotomy group, after performing a stab incision beside the piriform aperture, the 2-mm osteotome will be pushed through the soft tissue and the osteotomy will be carry out in a dotted manner.

Category

Treatment - Surgery

2

Description

In internal group after performing the incision in the nasal mucosa, the guarded osteotome will be pushed through the mucosa and osteotomy will carry out in a continuous manner.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Gandi Day Care Clinic

Full name of responsible person

Dr. Payam Varedi

Street address

No 35, Gandi avenue

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran university of medical sciences

Full name of responsible person

Dr. Gholamreza Shirani

Street address

4th floor, Ghods Avenue, Keshavarz bolivar

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tehran 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

Tehran university of medical sciences, Faculty of Dentistry,

Full name of responsible person

Dr Payam Varedi

Position

Resident in Oral and Maxillofacial Surgery

Other areas of specialty/work

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Position

Resident in Oral & Maxillofacial Surgery

Other areas of specialty/work

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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