

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of external and internal lateral nasal osteotomy on primary rhinoplasty complications

Protocol summary

Study aim

Comparison amount of the edema , ecchymosis , pain , scar , deformity and step after rhinoplasty between internal and external lateral osteotomy

Design

Clinical trial ; parallel groups; blinded ; randomised

Settings and conduct

This study is done on Qaem hospital ; within two years
This study is double blinded , patients and evaluators are blinded.

Participants/Inclusion and exclusion criteria

Patient without systemic disease ; without any surgery in face ; minimum age 18 and maximum age 35 previous nose surgery ; heart failure ; abnormal bleeding.

Intervention groups

Internal and external lateral osteotomy

Main outcome variables

Decrease edema , ecchymosis, step and pain after surgery

General information

Reason for update

Acronym

CEILNOPRC

IRCT registration information

IRCT registration number: **IRCT20191221045835N1**

Registration date: **2020-02-01, 1398/11/12**

Registration timing: **retrospective**

Last update: **2020-02-01, 1398/11/12**

Update count: **0**

Registration date

2020-02-01, 1398/11/12

Registrant information

Name

sara samiee rudi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3502 8092

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-02, 1396/02/12

Expected recruitment end date

2017-08-06, 1396/05/15

Actual recruitment start date

2017-05-02, 1396/02/12

Actual recruitment end date

2017-08-06, 1396/05/15

Trial completion date

2018-12-16, 1397/09/25

Scientific title

Comparison of external and internal lateral nasal osteotomy on primary rhinoplasty complications

Public title

Comparison of external and internal lateral nasal osteotomy on primary rhinoplasty complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ages between 18 -35 without any previous operation on face area without systemic disease

Exclusion criteria:

systemic disease high blood pressure abnormal bleeding heart disease previous nasal operation

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **80**

Actual sample size reached: **69**

Randomization (investigator's opinion)

Randomized

Randomization description

simple For randomization, sheets with title A and B are placed inside the box. A represent external osteotomy and B represent internal osteotomy. Patients randomly selected these sheets. The patients were visited by surgeon according to the selected tab.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient were blind . they choose a packet which has the surgery method. Assessors were blind ; by the codes were given to the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Vakil abad Blvd , Mashhad dental university

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2019-07-24, 1398/05/02

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1398.023

Health conditions studied

1

Description of health condition studied

The comparison of edema , ecchymosis , step and pain

between two groups of lateral internal and external osteotomy .

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The score of edema , ecchymosis , step and pain

Timepoint

2 , 7 and 21 days after surgery

Method of measurement

Evaluation of edema and ecchymosis with Kara and Gokalan

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Internal lateral osteotomy Surgical procedure under general anesthesia with Fentanyl , Halothane and Nesdonal.10 minutes before lateral osteotomy , Adrenalin(1/100/000) with Lidocaine (%1) injected into the desired area. All surgeries are done by a surgeon in Qaem hospital education center with a protocol of anesthesia.edema ,check out ecchymosis and step off deformity after 2,7 and 21days after surgery by a person(non-surgical surgeon).And observations were based on comparison with available forms in questionnaire rating.

Category

Treatment - Surgery

2

Description

Control group: External lateral osteotomy Surgical procedure under general anesthesia with Fentanyl , Halothane and Nesdonal.10 minutes before lateral osteotomy , Adrenalin(1/100/000) with Lidocaine (%1) injected into the desired area.All surgeries are done by a surgeon in Qaem hospital education center with a protocol of anesthesia.edema ,check out ecchymosis and step off deformity after 2,7 and 21days after surgery by a person(non-surgical surgeon).And observations were based on comparison with available forms in questionnaire rating.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Qaem hospital

Full name of responsible person

Dr.Mahdi gholami

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Ahmad abad Ave , Qaem hospital

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Full name of responsible person

Mahdi Gholami

Position

Assistant Professor

Latest degree

Specialist

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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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

Mashhad 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**

Mashhad University of Medical Sciences

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mahdi Gholami

Position

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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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