

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of subperiosteal tunnel in internal lateral osteotomy on the amount of periorbital edema and ecchymosis and subconjunctival ecchymosis after rhinoplasty

Protocol summary

Study aim

investigate the effect of subperiosteal tunnel in lateral internal osteotomy on periorbital edema and ecchymosis and subconjunctival ecchymosis after rhinoplasty.

Design

For patients on one side of the nose, before the lateral osteotomy, the subperiosteal tunnel will be created by the periosteal elevator, and on the opposite side, the osteotomy will be performed without creating the subperiosteal tunnel and maintaining the periosteal adhesion. In each patient, which side will be osteotomy by which method is chosen randomly. Edema and ecchymosis on the 2nd and 7th days after surgery will be evaluated using the standard 5-grade Gokalan-kara periorbital edema and ecchymosis system by a third surgeon who does not know how to perform the surgery.

Settings and conduct

Imam Khomeini Hospital in Ahvaz All patients underwent open rhinoplasty, and one side of the nose of the subperiosteal tunnel was created by periosteal elevator, and on the opposite side, without creating a subperiosteal tunnel and maintaining periosteal adhesion, osteotomy was performed, and at the end, a splint was placed on the patient. After the surgery, a new dose of dexamethasone 8 mg is prescribed for all patients

Participants/Inclusion and exclusion criteria

Patients in need of rhinoplasty surgery. Patients with coagulation problems and a family history of bleeding disorders, patients with high blood pressure and patients with a history of taking anticoagulant drugs, Patients with a history of previous rhinoplasty, trauma will be excluded from the study.

Intervention groups

In each patient, a subperiosteal tunnel will be created by a periosteal elevator on one side of the nose randomly before the lateral osteotomy, and on the opposite side,

the osteotomy will be performed without creating a subperiosteal tunnel and maintaining the adhesion of the periosteum.

Main outcome variables

edema and ecchymosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230624058563N1**

Registration date: **2023-08-21, 1402/05/30**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-21, 1402/05/30**

Update count: **0**

Registration date

2023-08-21, 1402/05/30

Registrant information

Name

Fatemeh AbediRad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 3333

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-11, 1402/05/20

Expected recruitment end date

2023-09-11, 1402/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of subperiosteal tunnel in internal lateral osteotomy on the amount of periorbital edema and ecchymosis and subconjunctival ecchymosis after rhinoplasty

Public title

The effect of subperiosteal tunnel in internal lateral osteotomy on the amount of periorbital edema and ecchymosis and subconjunctival ecchymosis after rhinoplasty

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Cleft Lip and Palate Patients

Exclusion criteria:

Patients with coagulation problems and family history of bleeding disorders Patients with a history of taking anticoagulant drugs Patients with high blood pressure Previous history of rhinoplasty, trauma

Age

No age limit

Gender

Both

Phase

0

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: 23

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization For patients who have a subperiosteal tunnel created on the right side of the nose and the left side has no tunnel, an even number is considered, and for patients who have a subperiosteal tunnel created on the left side of the nose and the right side has no tunnel, an odd number is considered. will be Then we will extract the relevant numbers from the table of random numbers according to the number of the studied sample. Each number is written on a card and placed in an envelope. The envelopes are sealed and the patient's number is written on each envelope. If the number inside the patient envelope is even, the subperiosteal tunnel is created on the right side, and if the patient number is odd, the subperiosteal tunnel is created on the left side.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluators of the outcome after the completion of the surgery did not know about the type and location of

the osteotomy

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Jundi Shapur Ahvaz University of Medical Sciences

Street address

Ahvaz, Golestan Boulevard, University City, Esfand St

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2023-05-02, 1402/02/12

Ethics committee reference number

IR.AJUMS.REC.1402.132

Health conditions studied**1****Description of health condition studied**

Patients in need of rhinoplasty surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

edema

Timepoint

Second and seventh days after surgery

Method of measurement

The objective scale based on Kara et al.'s study has 4 grades for edema

2**Description**

ecchymosis

Timepoint

Second and seventh days after surgery

Method of measurement

The objective scale based on Kara et al.'s study has 4 grades for ecchymosis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: a side of the nose, before the lateral osteotomy, the subperiosteal tunnel will be created by periosteal elevator

Category

Treatment - Surgery

2

Description

Control group: On the opposite side, osteotomy was performed without creating a subperiosteal tunnel and maintaining periosteal adhesion

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital in Ahvaz

Full name of responsible person

Fatemeh AbediRad

Street address

Ahvaz, 24 meter street, twenty four meter street, Ahvazian street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Fatemeh AbediRad

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The unwillingness of the researcher to publish data

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available