

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

comparison of the effect of two low to high lateral osteotomy methods, percutaneous and internal on the tear trough and scleral show in patients undergoing esthetic open rhinoplasty(a randomized clinical trial)

Protocol summary

Study aim

Comparison of the effect of high to low osteotomy by two percutaneous and internal methods on tear duct and scleral show in rhinoplasty patients.

Design

S blind RCT. The 110 envelopes with names A & B were given to patients before surgery. The patient before surgery, every one picked up one of them A: Percutaneous ; B: Internal

Settings and conduct

Imam Khomeini Hospital Surgery Center, Ahvaz. lateral osteotomy was performed through the skin by cutting a knife with a stab incision will be made. (Using a 2 mm osteotome and multi puncture approach) internal osteotomy will be performed with lateral osteotome ,by cutting the nasal mucosa in the pyriform opening and creating subperiosteal tunnel, maintaining Webster's triangle up to the intercanthal line,(low to high method). When the osteotomies are completed, a greenstick fracture will be created with gentle bilateral pressure.

Participants/Inclusion and exclusion criteria

inclusion criteria: 1 -Patient satisfaction. 2-Patients over 18 y. 3- No contraindications for rhinoplasty. 4- Narrow bridge width of the nose.5- People with systemically healthy; exclusion criteria: 1-graves ophthalmopathy (thyroid eye disease). 2- People with previous rhinoplasty. 3-People with suffering from chronic diseases. 4- People who have undergone other interventions such as neck and face lift or blepharoplasty. 5- history of fracture and trauma to the nose and face. 6- History of zygoma and naso-orbital-ethmoidal (NOE) bone fracture. 7-People with endocrine diseases, vasculitis, or infections around the eyes. 8- People with a prominent lacrimal bone edge (sunken globe). 9- History of burns (chemical, thermal, electrical, etc.) on the face and around the eyes. 10- Clear eyelid drooping with excess skin

Intervention groups

110 patients were divided into two groups of 55 people

Main outcome variables

Change in the size of tear trough and changes in scleral show

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220903055866N1**

Registration date: **2022-09-20, 1401/06/29**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-20, 1401/06/29**

Update count: **0**

Registration date

2022-09-20, 1401/06/29

Registrant information

Name

Raziyeh Moarefpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 918 348 2684

Email address

maryammoarefpour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-24, 1401/06/02

Expected recruitment end date

2022-10-07, 1401/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effect of two low to high lateral osteotomy methods, percutaneous and internal on the tear trough and scleral show in patients undergoing esthetic open rhinoplasty(a randomized clinical trial)

Public title

comparison of the effect of two low to high lateral osteotomy methods, percutaneous and internal on the tear trough and scleral show in patients undergoing esthetic open rhinoplasty(a randomized clinical trial)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient satisfaction Patients over 18 years old No contraindications for rhinoplasty surgery narrow bridge width of the nose People who are systemically healthy

Exclusion criteria:

1-graves ophthalmopathy (thyroid eye disease) People who have already undergone nose surgery People who were suffering from chronic diseases People who have undergone other interventions such as neck ,face lift or blepharoplasty history of fracture and trauma to the nose and face History of zygoma bone fracture and naso-orbital-ethmoid (NOE) FX People with endocrine diseases, vasculitis or infections around the eyes People with a prominent lacrimal bone edge (sunken globe) History of burns (chemical, thermal, electrical, etc.) on the face and around the eyes. Clear eyelid drooping with excess skin

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Single blind RCT. The 110 envelopes with names A & B were given to patients before surgery. The patient before surgery ,every one picked up one of them A: Percutaneous ; B: Internal

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 Jundi Shapur Ahvaz University of Medical Sciences

Street address

Karoon Sharghi

City

Ahvaz

Province

Khuzestan

Postal code

6136711885

Approval date

2022-08-23, 1401/06/01

Ethics committee reference number

IR.AJUMS.REC.1401.200

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

comparison of the effect of two low to high lateral osteotomy methods, percutaneous and internal

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

Tear trough size changes

Timepoint

1 , 3 months after surgery

Method of measurement

Sonography device Iexplorer (sonic S) with linear probe. High resolution of 75 micrometers and with a frequency of 10 MHz. Tissue depth in millimeter dimensions

2**Description**

Scleral show

Timepoint

1 , 3 months after surgery

Method of measurement

Photos were taken using a digital SLR camera (Canon 450D EOS) and scleral show area was measured with Adobe CS5 Ph software. The unit is Mm2

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: internal osteotomy; internal osteotomy will be performed with a left and right lateral osteotome , by cutting the nasal mucosa in the pyriform opening and creating a subperiosteal tunnel in the osteotomy line, maintaining Webster's triangle up to the intercanthal line(L to H) method. inner dressing will be placed for 24 hours .External Splints for 7 days and recommended ice pack for 24 hours

Category

Treatment - Surgery

2

Description

Intervention group: percutaneous osteotomy; approach: skin incision with stab incision. Osteotomy with 2mm osteotome and preservation of Webster Triangle. osteotomy by multi puncture and stamp-postage (L to h) bilaterally. inner dressing will be placed for 24 hours .External Splints for 7 days and recommended ice pack for 24 hours

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam Khomeini Hospital Surgery Center

Full name of responsible person

Ershad Hemmati

Street address

East Soroush Ave, Kianpars, Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Hojatollah Yousefi Manesh

Street address

West 5 Street, Kianpars, Ahvaz

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Email

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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

Raziyeh Moarefpour

Position

Resident of oral and maxillofacial surgery

Latest degree

Medical doctor

Other areas of specialty/work

Oral and maxillofacial surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Ershad Hemmati

Position

Associate professor

Latest degree

Specialist

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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

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

Yes - There is 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

Title and more details about the data/document

Information about the main outcome: The tear trough depth of each patient before surgery / 1 month after surgery / 3 months after surgery Size of Scleral Show in each patient before surgery / 1 month after surgery / 3 months after surgery

When the data will become available and for how long

The data access period is from October 1401

To whom data/document is available

It will be accessible to all researchers working in academic and educational institutions

Under which criteria data/document could be used

The collected data can be used to investigate the effects of rhinoplasty treatment on periorbital components

From where data/document is obtainable

Project manager Dr. ershad Hemmati and researcher Raziye Moarefpour maryammoarefpour@gmail.com hemmati1984@gmail.com

What processes are involved for a request to access data/document

The request will be sent after receiving the applicant's email and checking the mentioned items to use the data within a period of 3 days

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

Ahvaz University of Medical Sciences

Full name of responsible person

Raziye Moarefpour

Position

Resident of oral and maxillofacial surgery

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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