

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Post operative complications of two internal osteotomy methods in rhinoplasty: piezosurgery vs osteotomy

Protocol summary

Study aim

Comparative study of two methods of internal osteotomy in lateral nasal bones in rhinoplasty by osteotomy and piezosurgery

Design

The plan will attempt to compare internal osteotomy using osteotomy and piezoelectric surgery in two intervention groups. Patients are randomly divided into two groups. The consequences of pain and ecchymosis and swelling caused by nose bone osteotomy are examined.

Settings and conduct

This prospective study was conducted in patients referred to Ahvaz Imam Khomeini Hospital for rhinoplasty in the age range of 18 to 40 years old regardless of gender.

Participants/Inclusion and exclusion criteria

Population under study: Men and women between the ages of 18 and 40 require surgery for rhinoplasty. Entry Criteria: Rhinoplasty is a cosmetic effect. The age of the patients is between 18 and 40 years. Non-compliance criteria: clear deviation of hump nasal septum. Very high respiratory problems caused by past nose problems.

Intervention groups

Two intervention groups for internal osteotomy in lateral nasal bone in rhinoplasty by osteotomy and another, Pizzorhary

Main outcome variables

Pain, ecchymosis, swelling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170218032643N2**

Registration date: **2018-03-27, 1397/01/07**

Registration timing: **retrospective**

Last update: **2018-03-27, 1397/01/07**

Update count: **0**

Registration date

2018-03-27, 1397/01/07

Registrant information

Name

Amir Khosro Mohiti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3604 1717

Email address

mohiti.akh@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-03, 1396/01/14

Expected recruitment end date

2017-09-05, 1396/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Post operative complications of two internal osteotomy methods in rhinoplasty: piezosurgery vs osteotomy

Public title

Post operative complications of two internal osteotomy method in rhinoplasty: piezosurgery vs osteotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The age of the patient is between 18 and 40 years
Requires rhinoplasty
Exclusion criteria:
Clear deviation in the nasal septum Respiratory problems
due to nasal problems The history nose surgery

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: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups regardless of gender. All surgeries are performed by a surgeon. The study will be reviewed by a surgeon and a specialized assistant.

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 Ahvaz Jundishapur University of
Medical Sciences

Street address

Golestan Blvd, Ahvaz Jundishapur University of
Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2016-01-12, 1394/10/22

Ethics committee reference number

IR.AJUMS.REC.1395.531

Health conditions studied

1

Description of health condition studied

Rhinoplasty

ICD-10 code

J34

ICD-10 code description

Other and unspecified disorders of nose and nasal
sinuses

Primary outcomes

1

Description

Edema

Timepoint

The second and seventh day after surgery

Method of measurement

Grade 1: The upper and lower eyelids do not interfere with the pupil. Grade 2: A brief coverage of the pupils with some inflation in the eyelids. Grade 3: Complete coverage of the pupil with significant swelling in the eyelids. Grade 4: Complete Eye Closure

2

Description

Pain

Timepoint

First, second and third after surgery

Method of measurement

VAS scale

3

Description

Ecchymosis

Timepoint

Day two and seven after surgery

Method of measurement

The KARA method is used to assess ecchymosis. In this way, the results are categorized as follows: Grade 1: Kimos to 3/1 lower or upper eyelid, or both. Grade 2: Echimoses up to 2/2 lower or upper eyelid or both. Grade 3: Eclipse of the entire lower or upper eyelid, or both

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:

Category

Treatment - Surgery

2

Description

Intervention group:
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Amir Khosro Mohiti
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research and Technology of
Ahvaz Jundishapur University of Medical
Full name of responsible person
Mohammad Badavi
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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
Vice Chancellor for Research and Technology of Ahvaz
Jundishapur University of Medical
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
Amir Khosro Mohiti
Position
Resident of oral and maxillofacial surgery
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Contact

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Full name of responsible person

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Position

Resident of oral and maxillofacial surgery

Latest degree

Medical doctor

Other areas of specialty/work

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Email

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