

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Compassion of postoperative edema & echymosis in rhinoplasty patients who undergone lateral nasal osteotomy with two different kinds of instrument (piezosurgery versus hammer & osteotomy): clinical trial

Protocol summary

Summary

The aim of this study is to evaluate the ability of piezosurgery for lateral nasal osteotomy in rhinoplasty patients. Inclusion criteria are healthy volunteer patients & exclusion criteria are: people with severe nasal deformity resulted from trauma or congenital e.g lip and palate cleft; systemic diseases which interfere with coagulation & drug therapy. Patients selection are based on convenient sampling. Selection of patients will be performed from those people refer to maxillofacial clinic of Hamadan Besat Teaching Hospital. Sample size is about 20 patients that will be divided randomly into two equal groups. In the first group, lateral nasal osteotomy will be done by piezosurgery and the second group by hammer & osteotom. The operations will be performed under general endotracheal anesthesia. In the second & seventh postoperative days, the severity of periorbital oedema & echymosis will be rated based on Cara & Gokalan scoring system. The results will be compared in two groups by statistical analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060922638N1**

Registration date: **2015-07-17, 1394/04/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-17, 1394/04/26

Registrant information

Name

Kamal Faraji

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2015-07-16, 1394/04/25

Expected recruitment end date

2016-01-15, 1394/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compassion of postoperative edema & echymosis in rhinoplasty patients who undergone lateral nasal osteotomy with two different kinds of instrument (piezosurgery versus hammer & osteotomy): clinical trial

Public title

Rhinoplasty

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: healthy human volunteer Exclusion criteria: sever nasal deformity; systemic diseases which interfere with coagulation & drug therapy.

Age

No age limit

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

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 Hamedan University of Medical Sciences

Street address

Students Research Center, Hamadan University of Medical Sciences, Hamadan, Iran

City

Hamadan

Postal code

6517619651

Approval date

2015-05-23, 1394/03/02

Ethics committee reference number

UMSHA.REC.1394.861R

Health conditions studied

1

Description of health condition studied

edema

ICD-10 code

R60.0

ICD-10 code description

Localized oedema

2

Description of health condition studied

ecchymosis

ICD-10 code

R58

ICD-10 code description

Haemorrhage, not elsewhere classified

Primary outcomes

1

Description

Upper and lower eyelid edema

Timepoint

The second and seventh days after Rhinoplasty surgery

Method of measurement

According to the Cara & Gokalan scoring system

2

Description

Upper and lower eyelid ecchymosis

Timepoint

The second and seventh days after Rhinoplasty surgery

Method of measurement

According to the Cara & Gokalan scoring system

Secondary outcomes

empty

Intervention groups

1

Description

In control group, after performing an 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 case group, after performing an incision beside the piriform aperture, the piezoelectric instrument beak will be pushed through the tissue and osteotomy will be carry out in a continuous manner.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat teaching Hospital

Full name of responsible person

Dr. MohammadReza Jamalpour

Street address

Motahari Blvd.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

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Students Research Center, Hamadan University of
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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

Hamadan 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**

Hamadan University of Medical Sciences

Full name of responsible person

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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