

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of comparing periosteal Cutting and Elevating in the amount of bleeding, edema and ecchymosis in Lateral Osteotomy during Rhinoplasty

Protocol summary

Summary

Objectives: Periorbital edema and ecchymosis are common complications of Lateral Osteotomy in rhinoplasty. The aim of this study is to compare periosteal Cutting's and Elevating's effects on the amount of bleeding, edema and ecchymosis in Lateral Osteotomy during rhinoplasty. **Design:** The study is a not blinded random clinical trial with parallel assignment. **Setting and conduct:** The study will be conducted at Imam Reza Hospital) affiliated to Tabriz University of Medical Sciences(in Tabriz, Iran. **Participants** including major eligibility criteria: This study will be conducted on 80 volunteer eligible cases for rhinoplasty. All enrolled cases are white and from the same ethnic group. The exclusion criteria are known bleeding or coagulation disorder. **Intervention:** Operations will be under General Anesthesia (GA), using Total Intra Venous Anesthesia (TIVA) method. In one side of the nose, the approach will periosteal elevating before lateral osteotomy and the opposite side undergoes periosteal cutting without elevating. Side selection will be completely random. Injections to both sides will be performed in the same location and with the same dose. Also, similar osteotome with the same size will be applied for all patients by the same surgeon. **Main outcome measures (variables):** Intraoperative bleeding volumes will be measured in separate suction bottles for each side. Postoperative edema and ecchymosis will be assessed by the ward residents unaware of operation variations.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081123594N1**

Registration date: **2015-11-02, 1394/08/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-02, 1394/08/11

Registrant information

Name

Mehrnoush Mousavi-Aghdas

Name of organization / entity

Department of Otolaryngology, Children Hospital,
Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2006-12-21, 1385/09/30

Expected recruitment end date

2007-02-19, 1385/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparing periosteal Cutting and Elevating in the amount of bleeding, edema and ecchymosis in Lateral Osteotomy during Rhinoplasty

Public title

Comparison of two Methods of Rhinoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

This study will be conducted on 80 volunteer eligible cases for rhinoplasty. All enrolled cases are white and from the same ethnic group. The exclusion criteria are known bleeding or coagulation disorder

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 80

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 Tabriz University of Medical Sciences

Street address

Vice chancellor for research Office, third floor, No 2 Central Building, Tabriz University of Medical Sciences, University Street

City

Tabriz

Postal code

5165665931

Approval date

2006-12-22, 1385/10/01

Ethics committee reference number

85/3-5/7

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

Rhinoplasty

ICD-10 code

Y40, Y41,

ICD-10 code description

Complications of medical and surgical care

Primary outcomes**1****Description**

Amount of intra-operational bleeding

Timepoint

During surgery

Method of measurement

Intraoperative bleeding volumes will be measured in separate suction bottles for each side.

2**Description**

Edema

Timepoint

After surgery

Method of measurement

Postoperative edema will be assessed by the ward residents unaware of operation variations.

3**Description**

Ecchymosis

Timepoint

After surgery

Method of measurement

Ecchymosis will be assessed by the ward residents unaware of operation variations.

Secondary outcomes**1****Description**

No

Timepoint

No

Method of measurement

No

Intervention groups**1****Description**

Operations will be under General Anesthesia (GA), using Total Intra Venous Anesthesia (TIVA) method. In one side of the nose, the approach will periosteal elevating before lateral osteotomy

Category

Treatment - Surgery

2

Description

Operations will be under General Anesthesia (GA), using Total Intra Venous Anesthesia (TIVA) method. The opposite side undergoes periosteal cutting without elevating. Side selection will be completely random.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mehrnoosh Mousaviagdas

Street address

Imam Reza Hospital, in front of Tabriz university of medical science, University Street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Mohammad-Reza Rashidi

Street address

Vice chancellor for research Office, third floor, No 2 Central Building, Tabriz University of Medical Sciences, University Street

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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, Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mehrnoosh Mousaviagdas

Position

Assistant professor of otorhinolaryngology

Other areas of specialty/work

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Person responsible for updating data

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Position

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Other areas of specialty/work

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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