

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Comparison of rate and severity of nasal mucosal tear with internal and external lateral nasal osteotomy using endoscope

#### Protocol summary

##### Summary

The aim of this study is comparison of rate and severity of nasal mucosal tear with internal and external lateral nasal osteotomy using endoscope. 30 candidates of elective nasal surgery (10 males and 20 females) aged 20 to 30 years will be studied from April 2014 to August 2014 in this trial. Inclusion criteria: all candidates of elective nasal surgery aged 20 to 30 years. Exclusion criteria: 1. patients with history of nasal trauma 2. patients with history of nasal surgery 3. patients with severe deformity of nasal dorsum requiring complex osteotomies In this patients an external lateral osteotomy will be performed on one side and an internal lateral osteotomy will be performed on the alternate side. finally prevalence and severity of nasal mucosal tear will be compared between two sides and two groups. at the end of this study the technique of lateral nasal osteotomy with lower rate and severity of nasal mucosal tear will be demonstrated as the preferred technique.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014061013938N2**

Registration date: **2014-07-20, 1393/04/29**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-07-20, 1393/04/29

##### Registrant information

##### Name

Mohamadali Ghavimi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3335 5968

##### Email address

ghavimim@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz university of medical sciences, investigation secretary, research center of periodontal diseases

##### Expected recruitment start date

2014-04-21, 1393/02/01

##### Expected recruitment end date

2014-07-23, 1393/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of rate and severity of nasal mucosal tear with internal and external lateral nasal osteotomy using endoscope

##### Public title

effect of two different surgical techniques on amount of nasal mucosal tear

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

inclusion criteria: all candidates of elective rhinoplasty aged 20-30 years exclusion criteria: 1-patients with systemic diseases 2-history of previous nasal trauma 3-uncooperative patients 4-history of previous nasal surgery 5-patients with inflammation of nasal mucosa 6-patients with severe deformity of nasal dorsum who need complex methods of osteotomy

## Age

From **20 years** old to **30 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tabriz university of medical sciences/ethics committee

##### Street address

Daneshgah square,daneshgah avenue,Tabriz university of medical sciences

##### City

Tabriz

##### Postal code

#### Approval date

2014-06-29, 1393/04/08

#### Ethics committee reference number

9352

## Health conditions studied

### 1

#### Description of health condition studied

nasal mucosal tear

#### ICD-10 code

T81.2

#### ICD-10 code description

Accidental puncture and laceration during a procedure, not elsewhere classified

## Primary outcomes

### 1

#### Description

amount of nasal mucosal tear

#### Timepoint

immediately after intervention(intraoperatively)

#### Method of measurement

indirect view using endoscope

## Secondary outcomes

### 1

#### Description

amount of bleeding

#### Timepoint

immediately after completion of osteotomy

#### Method of measurement

measurment of blood volume (millileter)

## Intervention groups

### 1

#### Description

intervention group: after induction of general anesthesia and injection of 10 cc of 1:200000 epinephrine solution at lateral nasal walls and nasal dorsum the surgery was began,3mm osteotome without guard was introduced through skin at the midway between inner canthus and vestibule. when the cutting edge of osteotome reached bone the external osteotomy was initiated . In a blinded manner, another investigator used nasal endoscopy to detect nasal mucosal tears and reported them in millimeter (mm).

#### Category

Treatment - Surgery

### 2

#### Description

control group: after induction of general anesthesia and injection of 10 cc of 1:200000 epinephrine solution at lateral nasal walls and nasal dorsum the surgery was began. mucosal incision was made at the lateral nasal wall just above the junction of inferior turbinate.after introduction of 3mm guarded osteotome the internal osteotomy was initiated and completed at the level of the inner canthus . In a blinded manner, another investigator used nasal endoscopy to detect nasal mucosal tears and reported them in millimeter (mm).

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Maxillofacial surgery clinic

##### Full name of responsible person

Doctor alihosein mesgarzade

**Street address**

Daneshgah square,danshgah avenue,Imam reza teaching centre

**City**

Tabriz

mesgarcu@hotmail.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz university of medical sciences,dentistry faculty,maxillofacial surgery ward

**Full name of responsible person**

Doctor alihosein mesgarzade

**Position**

Maxillofacial surgery specialist/lecturer

**Other areas of specialty/work**

**Street address**

Daneshgah square,daneshgah avenue,dentistry faculty,maxillofacial surgery ward

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1335 5965

**Fax**

**Email**

mesgarcu@hotmail.com

**Web page address**

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Investigation secretary of tabriz university of medical sciences

**Full name of responsible person**

Doctor hassan soleimanpoor

**Street address**

Daneshgah avenue,investigation secretary of tabriz university of medical sciences

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Investigation secretary of 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/dentistry faculty

**Full name of responsible person**

Doctor alihosein mesgarzade

**Position**

Maxillofacial surgery specialist/lecturer

**Other areas of specialty/work**

**Street address**

Daneshgah square,daneshgah avenue,dentistry faculty,maxillofacial surgery ward

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1335 5965

**Fax**

**Email**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz unversity of medical sciences/dentistry faculty

**Full name of responsible person**

Saeed hajmohamadi

**Position**

Maxillofacial surgery resident

**Other areas of specialty/work**

**Street address**

Daneshgah square,daneshgah avenue,dentistry faculty

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1335 5965

**Fax**

**Email**

hajmohamadisaheed@yahoo.com

**Web page address**

**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*