

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparison of two cinch suturing techniques (classic & reinsertion) in preventing interalar widening before and six months after maxilla orthognathic surgery (advancement, impaction, advancement and simultaneous impaction)

#### Protocol summary

##### Study aim

Comparison of two techniques (classic & reinsertion cinch suturing) in preventing interalar widening before and six months after maxilla orthognathic surgery (advancement, impaction, advancement and simultaneous impaction) in patients referred to Bo Ali Hospital

##### Design

Patients undergo maxillofacial LeFort 1 orthognathic surgery by Bu Ali Hospital's maxillofacial surgery team. Patients are divided into three groups based on the type of Lefort surgery: advancement, impaction, advancement, and simultaneous impaction (17). Then, six months after the surgery, patients are asked to go to Bouali Hospital and the interalar width is measured again by a specialist assistant as a blind.

##### Settings and conduct

Comparison of two techniques (classic & reinsertion cinch suturing) in preventing interalar widening before and six months after maxilla orthognathic surgery (advancement, impaction, advancement and simultaneous impaction) in patients referred to Bo Ali Hospital

##### Participants/Inclusion and exclusion criteria

Patients older than 16 years who have completed written consent. Undergo orthognathic surgery including LeFort 1 maxillary osteotomy. Patients with advancements less than 5 mm and impactions less than 4 mm.

##### Intervention groups

Patients are divided into two groups of 15. In the first group, who underwent Lefort surgery, will be placed with the reinsertion cinch suturing technique, and the second group will be placed with the cinch suturing classic technique.

##### Main outcome variables

interalar width

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211029052908N1**

Registration date: **2021-11-26, 1400/09/05**

Registration timing: **prospective**

Last update: **2021-11-26, 1400/09/05**

Update count: **0**

##### Registration date

2021-11-26, 1400/09/05

##### Registrant information

##### Name

Seyedhossein Mirpoor

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2621 5676

##### Email address

dr.shmirpoor@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-30, 1400/09/09

##### Expected recruitment end date

2022-05-29, 1401/03/08

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of two cinch suturing techniques (classic & reinsertion) in preventing interalar widening before and six months after maxilla orthognathic surgery (advancement, impaction, advancement and simultaneous impaction)

### Public title

Comparison of two suturing methods to collect nasal base after maxillofacial orthognathic surgery(Maxillofacial correction surgery)

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients older than 16 years who have completed written consent Undergo orthognathic surgery including LeFort 1 maxillary osteotomy Patients with advancements less than 5 mm and impactions less than 4 mm.

#### Exclusion criteria:

Patients with cleft lip or palate or another congenital disorder. Patients with a history of maxillary surgery that may affect soft tissue due to scar tissue Patients with advancements greater than 5 mm and impactions greater than 4 mm

### Age

From **18 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)

Not 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 Tehran Azad University of  
Medical Sciences

##### Street address

Neystan 9, Pasdaran

##### City

Tehran

##### Province

Tehran

##### Postal code

1946853314

##### Approval date

2020-12-14, 1399/09/24

##### Ethics committee reference number

IR.IAU.DENTAL.REC.1399.241

## Health conditions studied

### 1

#### Description of health condition studied

Skeletal Deformity of Jaws

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Interalar width: The width of the base of the nose is the distance between the most prominent point on both sides of the blade of the nose, the ideal position of which should be 1 mm more than the distance between the two inner cantons of the eyes.

#### Timepoint

Six months after surgery

#### Method of measurement

Patients are divided into three groups based on the type of Lefort surgery: advancement, impaction, advancement, and simultaneous impaction (17). Then, six months after the surgery, patients are asked to go to Bouali Hospital and the interalar width is re-measured blindly by a specialist assistant. Third party assistant (except surgical team and project manager) is used after intra-surgical operation.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

alar cinch suture will be used by classic method and reinsertion cinch. For this purpose, a 33 mm needle with 2-0 Nylon monofilament thread of LINX brand made in India is used. In the classic method: the mucosa and muscle on one side are taken with nylon thread 2\_0, then the mucosa and muscle on the opposite side are taken directly without touching the skin of the muscle and mucosa on both sides and pulled together.

#### Category

Treatment - Surgery

## 2

### Description

Intervention group: alar cinch suture will be used by classic method and reinsertion cinch. For this purpose, a 33 mm needle with 2-0 Nylon monofilament thread of LINX brand made in India is used. In the reinsertion method: mucosa and The muscle on one side of the baselar is taken from inside the mouth and the needle comes out of the skin of the baselar area on one side and enters from the same area, and then the mucus, muscle and skin of the other side are taken in this way and finally The two sides of the base are pulled together and swing in the midline.

### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Boali Hospital

**Full name of responsible person**

Hosein Mirpour

**Street address**

Damavand Street,Emam Ali Highway,Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

17117

**Phone**

+98 21 3331 1106

**Email**

boali.hospital96@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Hosein Taffazoli Shadpour

**Street address**

Neyestan 9,Pasdaran

**City**

Tehran

**Province**

Tehran

**Postal code**

1946853314

**Phone**

+98 21 2256 4571

**Email**

Dr.shmirpoor@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Syedhossein Mirpoor

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

Neyestan 9,Pasdaran

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**Province**

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1946853314

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Resident

**Latest degree**

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

Islamic Azad University

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Dr.shmirpoor@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Comparison of two techniques (classic & reinsertion cinch suturing) in preventing interalar widening before and six months after maxilla orthognathic surgery (advancement, impaction, advancement and simultaneous impaction) in patients referred to Bo Ali Hospital

**When the data will become available and for how long**

Access period starts 6 months after the results are published

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

There is no other special case

**From where data/document is obtainable**

To the faculty research site at [www.ris.iau.ac.ir](http://www.ris.iau.ac.ir)

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

To the faculty research site at [www.ris.iau.ac.ir](http://www.ris.iau.ac.ir)

**Comments**