

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

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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

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1946853314

Phone

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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

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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

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

Islamic Azad University

Full name of responsible person

Seyedhossein Mirpoor

Position

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Fax**Email**

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

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

To the faculty research site at www.ris.iau.ac.ir

Comments