

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of changes in external airway resistance and basal alar size following Lefort 1 osteotomy with anatomical shaping of the nasal preform area in orthognathic surgery patients

Protocol summary

Study aim

The effect of allar base shaping on preventing unwanted consequences after surgery, such as increasing the width of the nose Investigating the effect of allar base shaping on improving respiratory status

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, including 30 patients in two groups of 15 people. Random allocation software was used for randomization.

Settings and conduct

study in patients with jaw problems will be performed to reduce the complications of this surgery in Al-Zahra and Ayatollah Kashani hospitals .All orthognathic surgeries will be performed by a surgeon with the same surgical team. They will be blind researchers and evaluators.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing orthodontic treatment are candidates for maxillofacial surgery (regardless of age and sex) The amount of movement of the upper jaw should not be more than 3 mm. Exclusion criteria: History of trauma and fracture in the middle of the face Patients with a history of congenital facial abnormalities (such as cleft palate)

Intervention groups

A typical Le Fort I osteotomy is performed in both groups. In order to prevent the flattening of the nasal alars (due to the fact that in the new maxilla the space for the fins has been reduced) in the control group for patients to control the position of the alarms from cinch suture Commonly used. In the intervention group, to control the position of the nasal passages, cutting and shaping the bone of the nasal cavity and preform is used to increase the space available for the nose. Cutting the bone of the nasal floor and the bone around the nose with a milling process will be 2 mm

Main outcome variables

The new method may improve the shape of the jawbone and ultimately improve postoperative breathing and reduce nasal congestion. It may also be effective in reducing nasal flattening.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200704047996N2**

Registration date: **2022-02-10, 1400/11/21**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-10, 1400/11/21**

Update count: **0**

Registration date

2022-02-10, 1400/11/21

Registrant information

Name

ali kazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4264 8448

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-28, 1400/11/08

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
Evaluation of changes in external airway resistance and basal alar size following Lefort 1 osteotomy with anatomical shaping of the nasal preform area in orthognathic surgery patients

Public title
Evaluation of the effect of anatomical shaping of the nasal preform area in orthognathic patients

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients undergoing orthodontic treatment and are candidates for maxillofacial surgery The amount of movement of the maxilla is less than 3 mm
Exclusion criteria:
 History of trauma and fracture in the middle of the face
 Patients with a history of congenital facial abnormalities (such as cleft palate)

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: 30

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to blind, the study of measurements is done by one person and then anonymous information will be provided to another person for examination.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar jerib St

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Province

Isfahan

Postal code

8975126354

Approval date

2022-01-16, 1400/10/26

Ethics committee reference number

IR.NUI.RESEARCH.REC.1400.416

Health conditions studied

1

Description of health condition studied

Complications of orthognathic surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Width of nasal alar base

Timepoint

3 months before surgery and 3 months after surgery

Method of measurement

Soft tissue calipers

2

Description

Respiratory function

Timepoint

3 months before surgery and 3 months after surgery

Method of measurement

rhinometry test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A typical Le Fort I osteotomy is performed to separate the maxilla and correct its position. In the intervention group, to control the position

of the nasal alar base, cutting and shaping the bone of the nasal cavity and preform is used to increase the space available for the nose. Cutting the bone of the nasal floor and the bone around the nose with a milling process will be 2 mm diameter

Category

Prevention

2

Description

Control group: A typical Le Fort I osteotomy is performed to separate the maxilla and correct its position. In the control group, the usual cinch suture is used to control the position of the alarms

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Surgery, Isfahan School of Dentistry

Full name of responsible person

Ali kazemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Siavash dasjerdi

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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

Esfahan University of Medical Sciences

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

Esfahan University of Medical Sciences

Full name of responsible person

Ali kazemi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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

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

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available