

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Sep 2026

Evaluation of changes in nasal profile after Lefort 1 osteotomy (maxillary advancement) with and without ANS reduction in class III skeletal patients referred to Bouali and Farhikhtegan Hospital in Tehran in 1400 and 1401: A Randomized Clinical Trial

Protocol summary

Study aim

Evaluation of changes in nasal profile after Lefort 1 osteotomy (maxillary advancement) With and without ANS reduction in skeletal patients of class III referred to Bouali and Farhikhtegan hospitals in Tehran in 1400 and 1401

Design

From the patients referred to the maxillofacial clinic, 26 class III skeletal patients are selected and randomly using balance block randomization with a sample size inside each block equal to 4 samples and random allocation inside the samples equally from both groups with the help of Rand software and Excell software are divided into two groups. The result of random allocation is done by a person other than the surgeon and evaluator and the type of allocation treatment is recorded on paper and for each sample is placed in a separate package with the sample sequential code. When surgery is performed with clinicians, they do not know the outcome of the allocation process in each sample until that moment.

Settings and conduct

pre-op lateral cephalometry is done and the analysis of study points and angles will be performed. On the day of surgery, two sets are prepared according to the two types of study intervention, and at that time, the envelope is opened according to the patient's assigned code, and the type of intervention. After 3 months, lateral cephalometry is requested from the same radiology center in the same position as before.

Participants/Inclusion and exclusion criteria

No history of maxillofacial surgery and need at least 3 mm maxillary advancement. Contrary to the mentioned conditions causes the patient to leave the study

Intervention groups

Intervention: For these people, Lefort 1 surgery is

performed with maxillary ANS reduction Control: For Irene patients, Lefort 1 surgery is performed without maxillary ANS reduction. ANS: Anterior nasal spine

Main outcome variables

Nasolabial angle and upper lip length

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210928052625N1**

Registration date: **2021-12-22, 1400/10/01**

Registration timing: **prospective**

Last update: **2021-12-22, 1400/10/01**

Update count: **0**

Registration date

2021-12-22, 1400/10/01

Registrant information

Name

Hosein Rastegarmoghaddam Shaldouzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3425 8913

Email address

dr.rastegarmoghaddam@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of changes in nasal profile after Lefort 1 osteotomy (maxillary advancement) with and without ANS reduction in class III skeletal patients referred to Buali and Farhikhtegan Hospital in Tehran in 1400 and 1401: A Randomized Clinical Trial

Public title

Evaluation of changes in nasal profile after Lefort 1 with and without ANS reduction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

History of maxillofacial surgery History of Rhinoplasty Surgery The amount of maxillary advancement should be more than 3 mm

Exclusion criteria:

History of Maxillofacial or Rhinoplasty surgery The amount of maxillary advancement is less than 3

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups using balanced block randomization with a sample size of 4 samples in each block and random allocation of samples in both groups with the help of Rand software, Excell software. The result of random allocation is done by a person other than the surgeon and evaluator (consultant of methodology and study statistics) and the type of allocation treatment is recorded on paper and each sample is placed in a separate package with a sample order code. When surgery is performed, clinicians who do not know the outcome of the allocation process in each sample until the time of surgery will open the packages.

Blinding (investigator's opinion)

Double blinded

Blinding description

The result of random allocation is done by a person other

than the surgeon and evaluator (consultant of methodology and study statistics) and the type of allocation treatment is recorded on paper and each sample is placed in a separate package with a sample order code. When surgery is performed, clinicians who do not know the outcome of the allocation process in each sample until the time of surgery will open the packages.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National Committee for ethics in biomedical research

Street address

13th floor, Block A, Ministry of Health and Medical Education, Simaye Iran Ave, South Falamak, Shahrake Gharb

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2021-06-09, 1400/03/19

Ethics committee reference number

IR.IAU.DENTAL.REC.1400.035

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

Skeletal Deformity of Jaws

ICD-10 code

M26.213

ICD-10 code description

Malocclusion, Angle's class III

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

Nasolabial Angle

Timepoint

Pre Op and 3 moths Post Op

Method of measurement

Lateral Cephalometric analysis of measurements

2

Description

upper lip length

Timepoint

Pre Op and 3 moths Post Op

Method of measurement

Lateral Cephalometric analysis of measurements

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Lefort 1 osteotomy with ANS reduction

Category

Treatment - Surgery

2

Description

Control group: Lefort 1 osteotomy without ANS reduction

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Buali Hospital

Full name of responsible person

Dr. Hosein Rastegarmoghaddam Shaldoozi

Street address

Damavand Ave, Imam Hosein Squ, Tehran

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Web page address

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2

Recruitment center

Name of recruitment center

Farhikhtegan Hospital

Full name of responsible person

Dr. Hosein Rastegarmoghaddam Shaldoozi

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Daneshgah Squ, Hesarak, Sattari Highway

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Web page address

<http://farhikhtegan.iautmu.ac.ir/fa>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Hosein Rastegarmoghaddam Shaldoozi

Street address

No.9, 9th Neyestan, Pasdaran Ave

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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

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

Hosein Rastegarmoghaddam Shaldouzi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Oral and Maxillofacial Surgery

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Position

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Other areas of specialty/work

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

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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)**

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

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

Data Dictionary

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