Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 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 Buali 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 advancemeny. 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 Rastegarmoghadam 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
City
Tehran
Province
Tehran
Postal code
17117
Phone
+98 21 3334 8036
Email
booali.hospital96@gmail.com
Web page address
http://bouali.iautmu.ac.ir/fa

2

Recruitment center
Name of recruitment center
Farhikhtegan Hospital
Full name of responsible person
Dr. Hosein Rastegarmoghaddam Shaldoozi
Street address
Daneshgah Squ, Hesarak, Sattari Highway
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Postal code
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Phone
+98 21 4486 7262
Email
farhikhteganhospital@gmail.com
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 Shalodoozi
Street address
No.9, 9th Neyestan, Pasdaran Ave
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1946853314
Phone
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dr.rastegarmoghaddam@hotmail.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
Hosein Rastegarmoghadam Shaldouzi
Position
Resident

Latest degree
Medical doctor
Other areas of specialty/work
Oral and Maxillofacial Surgery
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Person responsible for updating data

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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