

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Nasal Soft Tissue Changes Following Maxillary Lefort I Advancement Osteotomy with and without Impaction ; using 3D Photogrammetry, A before and after Clinical Trial

Protocol summary

Study aim

Determination of Nasal Soft Tissue Changes following Maxillary Lefort I Advancement, Determination of Nasal Soft Tissue Changes following Maxillary Lefort I Advancement with Impaction, And then Comparison of these two Parameters.

Design

Two arm parallel group not randomised clinical trial without Blinding, In 21 Patients

Settings and conduct

Patients undergoing orthognathic surgery in Ayatollah Taleghani and Farmaniyeh hospitals in Tehran. Three-dimensional images are going to obtain from patients by 3D optical Scanner pre-operation and 4 months post-operation.

Participants/Inclusion and exclusion criteria

Patients will undergo Maxillary Lefort I Advancement Osteotomy With and Without Impaction

Intervention groups

Group I : 11 Patients are going to treat by Maxillary Lefort I Advancement osteotomy only. Group II: 10 Patients are going to treat by Maxillary Lefort I advancement with Impaction Osteotomy

Main outcome variables

Nasal Soft Tissue Changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200726048214N1**

Registration date: **2020-09-12, 1399/06/22**

Registration timing: **retrospective**

Last update: **2020-09-12, 1399/06/22**

Update count: **0**

Registration date

2020-09-12, 1399/06/22

Registrant information

Name

Hamoun Sabri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3345 0736

Email address

hamounsbi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-22, 1398/05/31

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

2019-08-22, 1398/05/31

Actual recruitment end date

2020-07-21, 1399/04/31

Trial completion date

2020-07-21, 1399/04/31

Scientific title

Nasal Soft Tissue Changes Following Maxillary Lefort I Advancement Osteotomy with and without Impaction ; using 3D Photogrammetry, A before and after Clinical Trial

Public title

Nasal Changes Following Maxillary Advancement with and without Impaction, Using 3D imaging

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Class III Malocclusion, Candidate for Lefort I Maxillary Advancement With or without Maxillary Impaction Surgery.

Exclusion criteria:

Congenital diseases Cleft lip and palate and other syndromes history of facial trauma previous orthognathic surgery

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **21**

Randomization (investigator's opinion)

N/A

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 Shahid Beheshti Medical Sciences University

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-02-18, 1397/11/29

Ethics committee reference number

IR.SBMU.DRC.REC.1398.020

Health conditions studied

1

Description of health condition studied

Class III Malocclusion

ICD-10 code

M26.213

ICD-10 code description

Malocclusion, Angle's class III

Primary outcomes

1

Description

Nasal Soft Tissue Changes

Timepoint

Before Surgery and 4months Post-op

Method of measurement

The soft tissue variables will be extracted from the 3D images taken by the 3D face scanner and then their numerical values will be calculated by GOM Inspect 2019 software.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Maxillary Lefort I advancement Osteotomy without Impaction, Patients will undergo conventional Maxillary Lefort I advancement surgery without Impaction . 3D images of patient's faces before surgery and 4 months after surgery will be taken by a 3D Optical scanner.

Category

Treatment - Surgery

2

Description

Intervention group: Maxillary Lefort I advancement with Impaction Osteotomy, Patients will undergo conventional Maxillary Lefort I advancement with Impaction surgery . 3D images of patient's faces before surgery and 4 months after surgery will be taken by a 3D light scanner.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Farmanieh Hospital

Full name of responsible person

Hamoun Sabri

Street address

No 20 Andarzgoo Blvd, Shemiranat, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1578652369

Phone

+98 21 2815 2000

Email

webmail@farmaniehhospital.com

Web page address

<http://farmanieh-hospital.com/fa/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Farzin Sarkarat

Street address

Sarkarat clinic, Kaveh Blvd, district 3, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19585175

Phone

+98 21 2239 4855

Email

sarkarat@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

80

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hamoun Sabri

Position

Student, Faculty of Dentistry

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

No 23 Amid St, Zaferanieh, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985955817

Phone

+98 21 2241 1626

Email

Hamounsbi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hamoun Sabri

Position

Student, Faculty of Dentistry

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

No 23 Amid St, Zaferanieh, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985955817

Phone

+98 21 2241 1626

Email

Hamounsbi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hamoun Sabri

Position

Student, Faculty of Dentistry

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

No 23 Amid St, Zaferanieh, Tehran, Iran

City

Tehran

Province
Tehran
Postal code
1985955817
Phone
+98 21 2241 1626
Email
Hamounsbi@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

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

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

All data related to soft tissue variables of the nose will be available without mentioning the names, information and images of patients and only in the form of numerical data and related analyzes. It is worth mentioning that the biographical information of patients such as age, gender, race, etc. will be expressed without mentioning the names or pictures of the patients' faces.

When the data will become available and for how long

The data access period will start from the time the results are published.

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions as well as to people working in industry.

Under which criteria data/document could be used

1. Carrying out study and research in the field related to this study 2. Conducting review studies

From where data/document is obtainable

Applicants for information and documentation can apply in the following ways: 1- Email to: Hamounsbi@gmail.com 2- Phone call with the contact number: 00989123807579

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

Data and documentation are stored in obj and EXCEL files. Therefore, after confirming the request, these files will be provided to the applicant.

Comments