

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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

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## Person responsible for updating data

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**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**