

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Evaluation of mandibular condyle surface remodeling after orthognathic surgery in patients with Class III deformity Between 1400-1401

#### Protocol summary

Registration date: **2021-10-30, 1400/08/08**

Registration timing: **prospective**

#### Study aim

Evaluation of mandibular condyle surface remodeling after orthognathic surgery in patients with Class III deformity Between 1400-1401

Last update: **2021-10-30, 1400/08/08**

Update count: **0**

#### Design

Study of remodeling of mandibular condyle surfaces of 20 people between 20 and 40 years old who have Class III deformity and have referred to Bouali and Farhikhtegan Hospital in Tehran for mandibular setback surgery

#### Registration date

2021-10-30, 1400/08/08

#### Registrant information

##### Name

Farbod Jafari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2620 3975

##### Email address

farbodjafari1373@gmail.com

#### Settings and conduct

Samples of mandibular setback surgery with BSSO method with or without Lefort I Maxilla surgery located in Bouali and Farhikhtegan Hospital of Tehran Azad University are collected and compared by preoperative and 10 months postoperative CBCTs. In 3D Demand on software, the right and left condylar areas are isolated and 4 new images are created, which include right and left condyles before and after the operation. The condylar surfaces examined are the anterior, posterior, medial, and lateral surfaces, and the upper surface, which is compared to its counterpart in pre- and postoperative CBCTs.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

Healthy people between the ages of 20 and 40 with Class III deformity without severe facial asymmetry and degenerative joint disease.

#### Expected recruitment start date

2021-11-22, 1400/09/01

#### Expected recruitment end date

2023-03-20, 1401/12/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Intervention groups

Mandibular setback surgery by BSSO method with or without Lefort I maxillary surgery

#### Trial completion date

empty

#### Main outcome variables

Remodeling of mandibular condyle surfaces

#### Scientific title

Evaluation of mandibular condyle surface remodeling after orthognathic surgery in patients with Class III deformity Between 1400-1401

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211012052741N1**

##### Public title

Evaluation of mandibular condyle surface remodeling

after orthognathic surgery in patients with Class III deformity Between 1400-1401

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Patients with class III deformity Between the ages of 20 to 40

#### **Exclusion criteria:**

Severe facial asymmetry Degenerative joint diseases

### **Age**

From **20 years** old to **40 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **20**

### **Randomization (investigator's opinion)**

N/A

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Single

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of the School of Dentistry, Islamic Azad University of Tehran

##### **Street address**

No. 9, Neyestan 9, Pasdaran Ave., Tehran, Iran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1946853314

#### **Approval date**

2021-08-24, 1400/06/02

#### **Ethics committee reference number**

IR.IAU.DENTAL.REC.1400.063

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Patients with class III deformity

#### **ICD-10 code**

M26.213

#### **ICD-10 code description**

Malocclusion, Angle's class III

## **Primary outcomes**

### 1

#### **Description**

Remodeling of mandibular condyle surfaces

#### **Timepoint**

Before and 10 month after surgery

#### **Method of measurement**

Using CBCT and 3D Demand on software, the right and left mandibular condyle areas are isolated and 4 new images are created, which include right and left condyles before and after the operation.

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group:20 Healthy people between the ages of 20 and 40 with Class III deformity and without severe facial asymmetry and degenerative joint disease, will undergo mandibular setback surgery with BSSO method, with or without Lefort I Maxilla surgery, which will be carried out in Bouali and Farhikhtegan Hospital of Tehran Azad University. Data of the surgery will be collected and compared by preoperative and 10 months postoperative CBCTs. In "3D Demand on" software, the right and left condylar areas will be isolated and 4 new images will be created, which include right and left condyles before and after the operation. The condylar surfaces that will be examined by the software are 5 surfaces including the anterior, posterior, medial, and lateral surfaces, and the upper surface, which will be compared to its counterpart in pre- and postoperative CBCTs.

#### **Category**

Treatment - Surgery

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Booali hospital

##### **Full name of responsible person**

Farbod Jafari

##### **Street address**

Before Imam Ali HWY., Damavand Ave., Imam

Hossein Sq.  
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+98 21 3334 8036  
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booali.hostipal96@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Arash Azizi  
**Street address**  
No. 9, Neyestan 9, Pasdaran Ave., Tehran, Iran  
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1946853314  
**Phone**  
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**Email**  
Farbodjafari1373@gmail.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**  
Private  
**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**  
Farbod Jafari  
**Position**  
Resident  
**Latest degree**

Medical doctor  
**Other areas of specialty/work**  
Dentistry  
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No. 4, Athar street, Nelson Mandela Blvd  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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Islamic Azad University  
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**Fax****Email**

Farbodjafari1373@gmail.com

**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**

Not applicable

**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