

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Arash Azizi
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No. 9, Neyestan 9, Pasdaran Ave., Tehran, Iran
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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
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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Person responsible for updating data

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Fax**Email**

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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

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