

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of polyethylene prosthesis surgery on volume changes in mid-facial area in bouali hospital patients by 3D scanner

Protocol summary

Study aim

amount of volume increase of the mid-facial area affected by polyethylene prosthesis

Design

Clinical Trial without control group Patients are all grouped into a group and the same procedure and similar prosthesis are used

Settings and conduct

These surgeries are carried out at BouAli Hospital in Tehran and by a single surgeon Surgery is under general anesthesia and the prosthesis are placed in the appropriate place on over zygomatic bone using oral incisions and the prostheses are fixed to the bone by a titanium screw

Participants/Inclusion and exclusion criteria

Patients requiring surgical prosthetics referring to Boouli Hospital Patients should be free of systemic diseases, which are classified as ASA1 or ASA2 Patients have no history of previous surgery or trauma to the head and neck Patients who have an infection or displacement of the prosthesis after surgery are excluded Patients who have BMI changes in excess of one unit during the follow-up period are excluded

Intervention groups

The intervention involves the insertion of a polyethylene prosthesis onto a person's zygomatic bone This surgery is performed under general anesthesia via intraoral approach The registration of the three-dimensional shape of the face before and after the operation is performed by a three-dimensional scanner with a Structural Light system that does not cause any radiation or injury to the patient

Main outcome variables

volume changes in the malar and buccal regions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180515039664N1**

Registration date: **2018-05-28, 1397/03/07**

Registration timing: **prospective**

Last update: **2018-05-28, 1397/03/07**

Update count: **0**

Registration date

2018-05-28, 1397/03/07

Registrant information

Name

Sina Hakimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2272 9626

Email address

sinahakimi@irimc.org

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-05, 1397/03/15

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of polyethylene prosthesis surgery on volume changes in mid-facial area in bouali hospital patients by 3D scanner

Public title

Evaluation of the effect of polyethylene prosthesis on volume changes in mid-facial area

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients requiring surgical prosthetics referring to Boouli Hospital No systemic disease limiting ASA1 or ASA2 classifications No history of surgery or trauma in the head and neck area

Exclusion criteria:

Infection or displacement of the prosthesis after surgery
BMI changes over one unit in the follow-up period

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 15

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Azad University of Medical Science

Street address

No. 4, 9th Neyestan St., Pasdaran Ave.

City

Tehran

Province

Tehran

Postal code

19585175

Approval date

2017-03-12, 1395/12/22

Ethics committee reference number

IR.IAU.DENTAL.REC.1395,29

Health conditions studied

1

Description of health condition studied

Midface Deficiency

ICD-10 code

Q18.9

ICD-10 code description

Congenital malformation of face and neck, unspecified

Primary outcomes

1

Description

volume of the midfacial area

Timepoint

Measuring the volume of the face will be done before surgery and 5 months after surgery

Method of measurement

3D scanner device Structured Light (Sense™, 3D Systems Inc, Rock Hill, USA)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Surgical placement of polyethylene prosthesis Design M Malar Implants(MEDPOR MEDPOR™, Porex Surgical Inc, Newnan USA) Small 9507 9508 و 64)mm19mm3mm) and 3D scan of face surface

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Bouali Hospital

Full name of responsible person

Sina Hakimi

Street address

Damavand Ave., Imam Hossein Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Arash Azizi

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No. 4, 9th Neyestan St., Pasdaran Ave.

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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

Sina Hakimi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Maxillofacial Surgery

Street address

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Islamic Azad University

Full name of responsible person

Sina Hakimi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

Islamic Azad University

Full name of responsible person

Sina Hakimi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Email

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

In the initial form, personal information including name and surname and age, height and weight are recorded and a number assigned to each person The face scan information of each patient is stored to the computer with the name assigned After being unidentifiable, only the information on the main outcome is shared

When the data will become available and for how long

Starting data access is 6 months after the results are printed

To whom data/document is available

All people with a medical degree or working in health care organizations

Under which criteria data/document could be used

Any data analysis is allowed

From where data/document is obtainable

Applicants will submit their application in the order of priority to the following emails sinahakimi@irimc.org sinahakimi@yahoo.com thehakimi24@gmail.com

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

After receiving an request email, the datas will be sent within 5 to 7 days

Comments