Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 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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Tehran
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Postal code
۱۹۸۸۶۴۴۶۵۶
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+98 21 3331 1107
Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr Arash Azizi
Street address
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
No. 4, 9th Neyestan St., Pasdaran Ave.
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Person responsible for scientific inquiries

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Person responsible for updating data

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Medical doctor
Other areas of specialty/work
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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