Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effects of orthognathic surgery on perfectionism, mental health and quality of life

Protocol summary

Study aim
Determining the effects of orthogenetic surgery on mental health, quality of life and perfectionism of candidate patients

Design
This clinical trial consists of a group of 32 orthodontic surgery candidates in a non-randomly accessible manner performed on 32 orthodontic patients.

Settings and conduct
Candidate patients for maxillofacial surgery who refer to the clinic and surgical departments affiliated to Isfahan University of Medical Sciences and the office of the maxillofacial surgeon are evaluated in terms of entry and non-entry criteria. Eligible candidates will receive written consent. Orthognathic surgery is performed by a maxillofacial surgeon (executor of plan) at Al-Zahra Hospital in Isfahan.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18 to 50 years old; Persian speaker; minimum literacy to read and write and informed consent to participate in the study. Non-entry criteria: cleft lip and palate; severe congenital abnormalities; severe trauma injuries and major Psychiatric and neurological disorders.

Intervention groups
The intervention group are candidate patients for orthognathic surgery. The intervention is orthognathic surgery performed by a maxillofacial surgeon.

Main outcome variables
Quality of life scores; Depression scores; Anxiety; Stress; Perfectionism score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110815007339N4**
Registration date: **2022-01-22, 1400/11/02**
Registration timing: **retrospective**

Last update: **2022-01-22, 1400/11/02**
Update count: **0**

Registration date
2022-01-22, 1400/11/02

Registrant information

Name
Amrollah Ebrahimi

Name of organization / entity
Isfahan University of Medical Sciences, Isfahan, Iran

Country
Iran (Islamic Republic of)

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+98 31 3625 8818

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-15, 1398/10/25

Expected recruitment end date
2020-05-14, 1399/02/25

Actual recruitment start date
2020-05-04, 1399/02/15

Actual recruitment end date
2020-09-15, 1399/06/25

Trial completion date
2021-02-13, 1399/11/25

Scientific title
Effects of orthognathic surgery on perfectionism, mental health and quality of life

Public title
Orthognathic surgery and mental health and quality of life

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 50 years old Persian speaker Minimum literacy to read and write Consent to participate in the study
Exclusion criteria:
Cleft lip and cleft palate Abnormalities due to congenital disorder which necessitates surgeries Impairments due to severe trauma Major psychiatric and neurological disorders
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **63**
Actual sample size reached: **32**
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
Institutional Research Ethics committee. Isfahan University of Medical Sciences
Street address
Hezarjerib street
City
Isfaha
Province
Isfehan
Postal code
81746-73461
Approval date
2020-10-12, 1399/07/21
Ethics committee reference number
IR.MUI..RESEARCH.REC1399.455

Health conditions studied

1

Description of health condition studied
Dentofacial deformity
ICD-10 code
M26
ICD-10 code description
Dentofacial deformity

Primary outcomes

1

Description
Orthognathic Quality of Life Questionnaire
Timepoint
Before intervention (surgery) and six months after surgery
Method of measurement
Self-report questionnaire

2

Description
Depression
Timepoint
Before surgery and six months after surgery
Method of measurement
Self-report questionnaire

3

Description
Anxiety
Timepoint
Before and six months after surgery
Method of measurement
Self-report questionnaire

4

Description
Stress
Timepoint
Before and six months after surgery
Method of measurement
Self-report questionnaire

5

Description
Perfectionism
Timepoint
Before and six months after surgery
Method of measurement
Self-report questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: orthognathic surgeryAfter approving the plan in the research vice chancellor of Isfahan University of Medical Sciences and receiving the code of ethics from the ethics committee, patients who were candidates for orthognathic surgery and met the inclusion criteria were selected by referring to an oral and maxillofacial surgeon in medical centers affiliated to Isfahan University of Medical Sciences. . After gaining their trust and explaining the objectives of the research, written informed consent was obtained and questionnaires were completed. Orthognathic surgery performed according to the patient's problem and diagnosis of abnormality included mandibular, maxillary or both maxillofacial surgery performed by a maxillofacial surgeon during a session in the operating room of Al-Zahra Hospital. The type of operation was orthognathic surgery, known as jaw correction surgery or simply jaw surgery, and is designed to correct the condition of the jaw and face as well as a wide range of imbalance, asymmetry, asymmetry and facial fit to improve function and improve aesthetics. . Patients were followed up by a physician at least 6 months after surgery and a questionnaire was completed again.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral and Maxillofacial surgery ward in Al-Zahra Hospital

Full name of responsible person

Dr. Abbas Haghighat

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Soffeh Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan University of Medical Sciences

Proportion provided by this source

25

Public or private sector

Public

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

Esfahan University of Medical Sciences

Full name of responsible person

Abbas Haghighat

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The analyses of the data will be published as a scientific article.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable