

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

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

Protocol summary

Registration timing: **retrospective**

Study aim

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

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

Update count: **0**

Registration date

2022-01-22, 1400/11/02

Design

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

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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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.

Recruitment status

Recruitment complete

Funding source

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.

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

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

Scientific title

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110815007339N4**

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

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

Isfahan

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 surgery After 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

Dr. Shaghayegh Haghjoo Javanmard

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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

Contact

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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