

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparison of the accuracy of orthognathic conventional and 3-D printed surgical splints in maxillary position

#### Protocol summary

##### Study aim

Comparison of accuracy of conventional surgical orthognathic and 3-D printed splints in maxillary orientation

##### Design

10 candidates for orthognathic surgery are going to be sequentially picked based on their referral time to Tehran Buali hospital if they meet the study inclusion criteria. two interventions (acrylic and 3-d printed splints) are going to be performed on each ones jaw plaster models and the differences between maxilla movements will be measured. eventually each participant will undergo surgery with the guide of 3-d printed splint and postoperative cephalometric values will be compared with predictional ones.

##### Settings and conduct

the study field is" health care advancement" and the location is Tehran Buali hospital. no blindness is committed.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: 17-40 Yrs old patients, with dentofacial disharmony as a skeletal abnormality, who are candidates for orthognathic two jaw or maxillary single jaw surgery. exclusion criteria: patients with systemic comorbidities interfering with surgical process and outcome; candidates for maxillary segmental and mandibular single jaw surgeries.

##### Intervention groups

intervention is applied by conventional splint and 3-D printed one , and totally twice, for each of 10 participants. maxillary movements are evaluated on plaster models for both splints and each participant. postoperative radiographic maxillary orientation changes with 3-D printed splint are also going to be measured for each patient in all spacial dimentions.

##### Main outcome variables

Maxillary movements in spacial directions with each splint ; predictional cephalometric values ; postoperative cephalometric values.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170723035253N2**

Registration date: **2018-05-31, 1397/03/10**

Registration timing: **retrospective**

Last update: **2018-05-31, 1397/03/10**

Update count: **0**

##### Registration date

2018-05-31, 1397/03/10

##### Registrant information

##### Name

Omid Hamzezadeh tofighi

##### Name of organization / entity

Tehran Islamic Azad University-Dental Faculty

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3331 1107

##### Email address

ohtofighi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### Expected recruitment end date

2018-03-21, 1397/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the accuracy of orthognathic conventional and 3-D printed surgical splints in maxillary position

## Public title

Comparison of the accuracy of conventional and 3d printed orthognathic surgical splints in maxillary position

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients aged 17-40 Yrs old. Patients with dentofacial disharmony, as a skeletal abnormality. Patients candidated for two jaw or maxillary single jaw orthognathic surgery.

### Exclusion criteria:

Patients candidated for maxillary segmental and mandibular single jaw surgery. Patients with systemic comorbidities interfering with surgical process and outcome. Cleft lip/palate or craniofacial syndrome patients

## Age

From **17 years** old to **40 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **10**

More than 1 sample in each individual

Number of samples in each individual: **2**

two splints, an acrylic and a 3-D printed one are going to be evaluated for each participant.

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran azad university dental faculty

##### Street address

9th. Neyestan, Pasdaran Av.

##### City

Tehran

## Province

Tehran

## Postal code

1946853315

## Approval date

2017-06-18, 1396/03/28

## Ethics committee reference number

IR.IAU.DENTAL.REC.1396,3

## Health conditions studied

### 1

#### Description of health condition studied

3-d printed surgical splint

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

maxillary movements

#### Timepoint

preoperative and postoperative

#### Method of measurement

calipper: protractor

## Secondary outcomes

### 1

#### Description

surgical splints

#### Timepoint

preoperative and postoperative

#### Method of measurement

visual

## Intervention groups

### 1

#### Description

Control group: conventional acrylic splint

#### Category

Treatment - Devices

### 2

#### Description

Intervention group: 3d printed splint

#### Category

Treatment - Devices

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Tehran Buali hospital

**Full name of responsible person**

Farzin Sarkarat

**Street address**

Buali hospital, Damavand Ave.

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Farzin Sarkarat

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Sarkarat@hotmail.com

**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**

Omid Hamzezadeh Tofighi

**Position**

Oral and maxillofacial surgery resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Oral and maxillofacial surgery

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Omid Hamzezadeh Tofighi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Oral and maxillofacial surgery

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**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**

Undecided - It is not yet known if there will be a plan to make this available

**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