

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Study of buccal bone dimensional changes by Flapless immediate implantation and filling the buccal gap space with xenograft material by Cone beam computed tomography Technique

#### Protocol summary

##### Summary

This is an open, randomized, controlled, experimental Clinical Trial study with 32 patients in two parallel groups. The Main Objective: Study of buccal bone dimensional changes in Flapless immediate implantation by CBCT. Secondary Objective: Evaluation the effects of xenograft on bone remodeling. Inclusion criteria: Patients with implants request in the anterior maxillary area; Patients over 18 years; At least 3-5 mm keratinized gingiva and confirmed the presence of buccal bone after tooth extraction. Exclusion criteria: patients with any systemic disease which affecting the healing process; or any active infection in the region or acute apical lesions; And probing depth more than 4 mm in the adjacent teeth. After local anesthesia tooth removal was carried out atraumatic without elevation of a mucoperiosteal flap and with use of periosteal elevator and forceps, then a curette is used to ensure the integrity of the buccal bone plate. Standard drilling procedures are performed with Dentium system. The platforms of the implants were located 1.0-2.0 mm below the buccal bone crest level. The width of the gap between the implant surface and the inner and outer side of the bone wall and the buccal bone thickness at crest and 2 mm under it will be measure using a calliper and gauge, then the space will be filled by xenograft or remained without any material and tightening healing abutment then suture the area at final. The dimension of buccal bone plate will be assessed by CBCT at three time points: pre-surgery (T0), 24 h after surgery (T1), and 4 months postoperative (T2). Measurements will be taken at the cross sectional views in the middle of the anterior maxillary teeth.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201606188898N3**

Registration date: **2016-09-09, 1395/06/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-09-09, 1395/06/19

##### Registrant information

###### Name

Mojgan Paknejad

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8801 5801

###### Email address

mpaknejad@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2016-03-19, 1394/12/29

##### Expected recruitment end date

2017-01-18, 1395/10/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of buccal bone dimensional changes by Flapless

immediate implantation and filling the buccal gap space with xenograft material by Cone beam computed tomography Technique

#### Public title

Evaluation of the bone dimensional changes in immediate implant placement by CBCT

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Patients with implants request in the anterior maxillary area; Patients over 18 years; optimal oral hygiene; At least 3-5 mm keratinized gingiva and confirmed the presence of buccal bone after tooth extraction. Exclusion criteria: patients with any systemic disease which affecting the healing process; Smoker; Bruxer; And also any active infection in the region or acute apical lesions; And probing depth more than 4 mm in the adjacent teeth or the presence of the implant adjacent the area.

#### 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: **32**

#### Randomization (investigator's opinion)

Randomized

#### 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 University of Medical Sciences

###### Street address

Central Organization of Tehran University of Medical Sciences, keshavarz Blvd, Qods Ave

###### City

Tehran

###### Postal code

##### Approval date

2016-08-06, 1395/05/16

#### Ethics committee reference number

IR.TUMS.VCR.REC.1395.389

### Health conditions studied

#### 1

##### Description of health condition studied

Study of buccal bone dimensional changes of the missing teeth in the maxillary anterior region

##### ICD-10 code

K08.1

##### ICD-10 code description

Loss of teeth due to accident, extraction or local periodontal disease

### Primary outcomes

#### 1

##### Description

buccal bone dimensional changes at the crest and 2mm under the crest

##### Timepoint

Immediately after implant placement and 4 months after treatment.

##### Method of measurement

By using CBCT radiography

### Secondary outcomes

#### 1

##### Description

Buccal bone height changes

##### Timepoint

Immediately after implant placement and 4 months after treatment.

##### Method of measurement

By using CBCT radiography

### Intervention groups

#### 1

##### Description

Filling the gap with xenograft following implant placement

##### Category

Treatment - Drugs

#### 2

##### Description

Do not use bone material in the control group

##### Category

Treatment - Drugs

### Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Dental School, Tehran University of Medical Sciences

**Full name of responsible person**

Mr. Hossein Sabohi

**Street address**

Enghelab Square, North Karegar Street

**City**

Tehran

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mrs Samaneh Zolfaghari

**Street address**

Central Organization of Tehran University of Medical Science, keshavarz Blvd, Qods Ave

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Samira Hajheidary

**Position**

DDS, Postgraduate student of Periodontology

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## Person responsible for scientific inquiries

### Contact

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**Web page address**

## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*