

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

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Phone

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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

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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

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

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Person responsible for scientific inquiries

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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