Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Study of buccal bone dimensional changes by Flapless immediate implantation and filling the buccal gap space with xenograft material by Cone bean 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 dimentional 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 periotome 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 wil be filled by xenograft or remained without any material and tightening healing abutment then suture the area at final. The dimention 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

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Mojgan Paknejad
Name of organization / entity
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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 bean 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 dimentional 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
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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