Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Buccal bone Dimensional changes in immediate implant placement with and without bone graft with immediate provisionalization: A Randomized Clinical Trial

Protocol summary

Study aim

Evaluation of Buccal bone dimensional changes in immediate implant placement with and without bone graft with immediate provisionalization

Design

A randomized clinical trial with control and intervention groups, with parallel groups, one-way blind, Balanced Block Randomization of samples with 4 blocks size, on 30 patients

Settings and conduct

this study will be performed on patients who are candidates for anterior tooth extraction and immediate implant placement at a private clinic. After evaluating the patients according to the inclusion and exclusion criteria, an immediate implant with an immediate temporary prosthesis with and without a bone graft will be placed at the tooth extraction site and then a radiographic evaluation will be done to measure the bone changes.

Participants/Inclusion and exclusion criteria

inclusion criteria for this study are as follows: 1) Patients require extraction of an anterior maxillary tooth and the possibility of immediate placement of implants in the same site 2) Existence of buccal bone and 3) Gap space more than 2 mm between the implant and buccal bone. Similarly, exclusion criteria include 1) the presence of periodontal disease 2) the presence of systemic or local diseases that may interfere with bone repair (including diabetes, osteoarthritis, hypothyroidism, hyperparathyroidism, and osteoporosis) 3) Use of drugs that prevent implant placement or interfere with implant osteointegration (including bisphosphonates) 4) Pregnancy 5) Drug Addiction and smoking 6) Acute infection at the implant site 7) Patient under Radiotherapy and 8) patients with parafunctional habits such as Bruxism or Clenching

Intervention groups

1) Intervention group: Immediate implant placement + SigmaGraft-InterOss xenograft made in the USA 2) Control group: Immediate implant placement + without any bone graft material.

Main outcome variables

bone dimensional changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211119053106N1**
Registration date: **2021-12-06, 1400/09/15**
Registration timing: **prospective**

Last update: **2021-12-06, 1400/09/15**
Update count: **0**

Registration date

2021-12-06, 1400/09/15

Registrant information

Name

Salar Chaychi Salmasi

Name of organization / entity

Department of Research and Development, Farinroshaan Medical & Health Co. LTD., Tehran, Iran

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-08-22, 1401/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Buccal bone Dimensional changes in immediate implant placement with and without bone graft with immediate provisionalization: A Randomized Clinical Trial

Public title

Buccal bone Dimensional changes in immediate implant placement

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients require removal of a maxillary anterior tooth and the possibility of immediate implant placement in the same site presence of buccal bone Gap space greater than 2 mm between implant and buccal bone

Exclusion criteria:

periodontal disease presence of systemic or local diseases that may interfere with bone repair Use of drugs that prevent implant placement or interfere with implant osteointegration Pregnancy addiction to Drug and smoking Presence of acute infection at the implant site Patient undergoing radiotherapy Patients with parafunctional habits such as Bruxism or Clenching

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly allocated (1:1) to group 1 (with bone graft) and group 2 (without bone graft). The randomization sequence will be generated by an independent investigator using computer software (www.randomization.com). Balanced Blocked randomization will be used, with a block size of 4. The surgeon will open sequentially numbered, sealed envelopes only after the implants will be inserted on the day of the surgeries. Although the surgeon will be aware of the allocated arm, the radiographic outcome assessor will be kept blinded to the allocation.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants (patients) are completely blind to whether they are in the control or intervention group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Islamic Azad University - Dental Branch Tehran - Iran

Street address

No. 9, School of Dentistry, Tehran Azad University of Medical sciences, 9th Neyestan, Pasdaran Ave

City

Tehran

Province

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Postal code

1946853314

Approval date

2021-11-10, 1400/08/19

Ethics committee reference number

IR.IAU.DENTAL.REC.1400.096

Health conditions studied

1

Description of health condition studied

Immediate implant

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Bone dimensional Changes

Timepoint

At the beginning of the study and 6 months after the intervention (immediate implant placement)

Method of measurement

Cone Beam Computed Tomography Pictures

Secondary outcomes

1

Description

Secondary outcomes: 1) Implant failure: Any implant that

is removed after placement due to mobility, progressive marginal bone resorption, infection, or any mechanical complication (e.g., implant fracture). 2) Prosthesis failure: All prosthesis that fail with the implant or can not be placed due to implant failure or will be replaced for any reason. 3) Biological or prosthetic complications

Timepoint

6 months after intervention (implant placement)

Method of measurement

Clinical examination and Cone Beam Computed Tomography images

Intervention groups

1

Description

Intervention group: Immediate implant placement + placement of SigmaGraft-InterOss bone graft material made in the USA in the distance between implant and buccal bone.

Category

Treatment - Surgery

2

Description

Control group: Immediate placement of implant + without bone graft

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

school of dentistry, Tehran Azad University of Medical Sciences

Full name of responsible person

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Recruitment center

Name of recruitment center

Dorsa Private Dental Clinic

Full name of responsible person

Ali Hassani

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Amin Tower, Asef, Zaferanie,Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

Islamic Azad University

Proportion provided by this source

100

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

Islamic Azad University

Full name of responsible person

Salar Chaychi Salmasi

Position
Dentistry Student
Latest degree
A Level or less
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is 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
Not applicable
Title and more details about the data/document
All potential data can be shared after the participants are unidentifiable
When the data will become available and for how long
Access period starts from 2024
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
The data can be used for scientific researches
From where data/document is obtainable
Salar Chaychi Salmasi 0098 9143439375
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What processes are involved for a request to access data/document
After submitting the request, the request will be reviewed and answered as soon as possible.
Comments