

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of alveolar ridge dimension changes after immediate implant placement with and without bone grafting

Protocol summary

Study aim

Radiographic evaluation of the changes in alveolar ridge dimensions after immediate implant placement with and without the use of bone materials in a 4-months follow-up. Evaluation of the changes in the thickness of the buccal bone plate, buccal gap distance and the width buccolingual ridge, 2 days and 4 months later of implant placement in the 0, 2 and 4 mm from the implant platform, by cone-beam computed tomography in both groups.

Design

The clinical trial has a control group with randomized parallel groups without blinding, phase 2-3 on 30 implants, 15 implants in the test and the 15 implants in the control group.

Settings and conduct

Our patients include those who refer to Shahed Dental School and a private clinic, who need their teeth extracted and immediate implant placement. Before the operation, 0.2% chlorhexidine mouthwash is given for 60 seconds. After injection of anesthesia with 1/100000 lidocaine, atraumatic extraction of the tooth is performed in a flapless manner, and the silent walls are evaluated to confirm the health of the buccal bone plate. Drilling is done in order to place the bone level implant in the correct position and the implants are inserted in the lingual position and at a distance from the buccal plate.

Participants/Inclusion and exclusion criteria

Patients needing extraction and immediate implant placement without uncontrolled systemic disease, and with a intact buccal plate of the tooth after extraction.

Intervention groups

The use of bone graft material in the buccal distance gap in the test group and the blood clot filling in the control group are evaluated by radiography.

Main outcome variables

Buccal plate thickness; the buccal gap distance from the inner wall of the buccal plate to the external surface of the implant and the width of ridge buccolingual in the

implant platform and 2 and 4 mm more apically were measured with using CBCT.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221218056849N1**

Registration date: **2023-01-28, 1401/11/08**

Registration timing: **retrospective**

Last update: **2023-01-28, 1401/11/08**

Update count: **0**

Registration date

2023-01-28, 1401/11/08

Registrant information

Name

hasan Semyari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2248 5673

Email address

h.semyari@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-20, 1401/06/29

Expected recruitment end date

2023-01-19, 1401/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of alveolar ridge dimension changes after immediate implant placement with and without bone grafting

Public title

Evaluation of using bone material effects by Immediate implant placement

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

No Systemic disease Intact buccal bone plate

Exclusion criteria:

Uncontrolled systemic disease Heavy smoking The buccal bone plate loss Pregnancy and breastfeeding

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

More than 1 sample in each individual

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

30 implant in 15 patient

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block randomization method is used, so that thirty teeth with intact buccal bone plate selected that they need to extract and fresh socket implantation, they are divided into two groups of 15, such that odd teeth with odd numbers are in the first group and the teeth with even numbers are in the second group. In the first group, bone powder is placed at the same time as immediate implant insertion and don't use bone powder in the second group. There is no possibility of blinding the surgeon and the radiologist in this study, because it is obvious that the use and non-use of bone graft can be seen for both.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In this study, allograft bone graft materials made in Iran are used in gap distance the immediate implant.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahed University

Street address

No 71, itally street , Shahed School of Dentistry ,tehran iran

City

Tehran

Province

Tehran

Postal code

1417755366

Approval date

2021-11-01, 1400/08/10

Ethics committee reference number

IR.SHAHED.REC.1400.094

Health conditions studied**1****Description of health condition studied**

Changes in buccal plate thickness and buccal gap with immediate implant insertion

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Buccal gap distance in immediate implant

Timepoint

2 days and four months later

Method of measurement

CBCT radiology device

2**Description**

The width of the buccolingual ridge

Timepoint

2 days and four months later

Method of measurement

CBCT radiology device

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In this study, after inserting bone level immediate implant, buccal gap in the immediate

implant filling with bone powder of the Iranian tissue products (Regen) with a size of 500-1000, and then the location of the surgery with healing abutment and stitching .

Category

Treatment - Surgery

2

Description

Control group: In this study, after inserting bone level immediate implant, buccal gap in the immediate implant is filled naturally with blood clot and without using bone powder, and then the surgical site is closed with a healing abutment and suture.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahed dental university and a private clinic

Full name of responsible person

Hasan Semyari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr. Shahryar Bijani

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Persian Gulf highway in front of Imam Khomeini shrine

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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

Shahed 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

Shahed University

Full name of responsible person

Hasan Semyari

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The principle of protecting the medical secrets of patients

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