

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Dimensional changes of soft tissue following immediate flapless implant placement and provisionalization with or without xenograft: A Randomized Clinical Trial

Protocol summary

Study aim

Determination of soft tissue changes in immediate implant placement with and without xenograft bone graft with the immediate temporary prosthesis in patients referred to the Department of Oral and Maxillofacial Surgery, School of Dentistry, Islamic Azad University of Medical Sciences and Private Clinic in 1400

Design

A clinical trial with parallel case and control groups, one-way blind, randomized, on 34 patients, Paired means power option of PASS 11 software was used for randomization

Settings and conduct

Patients undergo extraction of one of their anterior teeth in the dental area 14-24. They receive an immediate implant. case group underwent xenografting and the healing placement, but the control group without xenograft. taking impression is done to make a provisionalization and after 2 weeks, it will be placed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: extraction of one of the maxillary anterior teeth in the cosmetic zone (number of teeth 14-24) and placement of immediate implants with provisionalization; Continuation of the buccal wall bone of the extracted tooth socket with sufficient thickness; Existence of more than 2 mm gap between the implant and the socket buccal wall Exclusion criteria: Periodontal disease; Presence of systemic or local diseases that are opposed to implant placement; Pregnancy; Cigarette and drug addiction; Presence of acute infection at the implant site; Patient undergoing radiotherapy; Use of drugs that disrupt bone and gingival tissue repair; Patients with parafunctional habits such as Bruxism or Clenching

Intervention groups

- 1) Case group: receiving immediate implant+bone graft
- 2) Control group: receive immediate implants

Main outcome variables

The thickness and height of the buccal soft tissue of the implant area, in both case and control groups, during the evaluation period of 3 and 6 months.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211115053065N1**

Registration date: **2022-01-01, 1400/10/11**

Registration timing: **prospective**

Last update: **2022-01-01, 1400/10/11**

Update count: **0**

Registration date

2022-01-01, 1400/10/11

Registrant information

Name

Mehrnoosh Meshkatalaasadat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4403 9543

Email address

mehrnooshmeshkat@gmail.com

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

Dimensional changes of soft tissue following immediate flapless implant placement and provisionalization with or without xenograft: A Randomized Clinical Trial

Public title

Effect of the xenografting on the buccal soft tissue dimensions of the immediate implant

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients prone to extract one of the maxillary anterior teeth in the cosmetic zone (number of teeth 14-24) and placement of immediate implants with provisionalization Continuation of the buccal wall bone of the extracted tooth socket with sufficient thickness after tooth extraction Existence of more than 2 mm gap between the implant and the socket buccal wall

Exclusion criteria:

Periodontal disease Presence of systemic or local diseases that are opposed to implant placement (diabetes, hyperthyroidism, hyperparathyroidism, and osteoporosis) Pregnancy Cigarette and drug addiction Presence of acute infection at the implant site Patient undergoing radiotherapy Use of drugs that disrupt bone and gingival tissue repair 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: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

the selected patients will be divided into two groups by the Balanced block randomization method with a size of 4 blocks. 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 at the day of surgeries. Although the surgeon will be aware of the allocated arm, soft tissue dimensional changes outcome assessor will be kept blinded to the allocation.

Blinding (investigator's opinion)

Single blinded

Blinding description

the selected patients are unaware of their assignment to the case group (performing xenograft bone graft) or the control group (not performing xenograft bone grafting).

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Azad University of Medical Sciences - Dental branch

Street address

No.16, Nastaran av, second Golha st, Elahi st, Ayatollah kashani blv, Sadeghiye sq

City

Tehran

Province

Tehran

Postal code

1471847495

Approval date

2021-11-13, 1400/08/22

Ethics committee reference number

IR.IAU.DENTAL.RED.1400.097

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

Severe gingival resorption after implant treatment in the maxillary cosmetic area

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

Changes in the height of gingival tissue in the mesial, middle and distal areas of the buccal area of the implant from the edge of the gingival margin

Timepoint

2 weeks, 3 months and 6 months after implant placement

Method of measurement

Periodontal probe with the help of stent and 15-end file with Rabrastop

2

Description

Changes in the thickness of the gingival soft tissue at intervals of 4 and 8 mm from the gingival margin in the mid buccal area of the implant

Timepoint

2 weeks, 3 months and 6 months after implant placement

Method of measurement

Periodontal probe with the help of stent and 15-end file with Rabrastop

Secondary outcomes

1

Description

Patient satisfaction with implant treatment

Timepoint

2 weeks and 6 months after implant placement

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: After extracting the specified tooth, the patients received a Dentium brand implant made in South Korea, the gap between the socket buccal wall and the implant surface will then be filled with US-made SigmaGraft-InterOss xenograft material. After placing the implant, the surgeon takes an impression of the implant, opposing arch impression, and jaw records. on both implant and bone graft, the healing abutment is put. it will be removed 2 weeks after placing the implant, and provisionalization will be replaced.

Category

Treatment - Surgery

2

Description

Control group: After extracting the specified tooth, the patients received a Dentium brand implant made in South Korea, and then the gap between the socket buccal wall and the surface of the implant will be left empty. After implant placement, the surgeon takes an impression of the implant, opposing arch impression, and jaw records. on the implant, the healing abutment is put. it will be removed 2 weeks after placing the implant, and provisionalization will be replaced.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Islamic Azad University of Tehran

Full name of responsible person

mehrnoosh meshkat alsadat

Street address

Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Islamic Azad University of Tehran, No.4, 9 Neyestan Ave, Pasdaran Blv, Tehran, Iran

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Phone

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Email

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

mehrnoosh meshkat alsadat

Street address

Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Islamic Azad University of Tehran, No.4, 9 Neyestan Ave, Pasdaran Blv, Tehran, Iran

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Email

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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

mehrnoosh meshkat alsadat

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Medical Education

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Faculty member of the Department of Oral and Maxillofacial Surgery, School of Dentistry, Islamic Aza

Latest degree

Medical doctor

Other areas of specialty/work

Medical Education

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Person responsible for updating data

Contact

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Full name of responsible person

Mehrnoosh Meshkat alsadat

Position

Dental Student, School of Dentistry, Azad University of Tehran

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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