Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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 Meshkatalsaadat

Name of organization / entity

Country

Iran (Islamic Republic of)

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+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 dimentional 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 sucket 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 sucket buccal walll 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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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
City
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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

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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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Position
Dental Student, School of Dentistry, Azad University of Tehran

Latest degree
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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