Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The comparison between autogenous tooth and autogenous bone graft for phenotype modification around immediate implants

Protocol summary

Study aim
To compare the radiographic and clinical outcomes of autogenous dentin graft versus autogenous bone graft for modifying the peri-implant periodontal phenotype around immediately placed implants.

Design
A randomized, single-blind, parallel-group, controlled clinical trial, conducted on 38 patients. For randomization, statistical software (SPSS Random Number Generator or Random Allocation Software) was used with a block randomization method.

Settings and conduct
This single-blind randomized clinical trial will enroll patients needing immediate anterior maxillary implants. The buccal gap will be filled with autogenous dentin (intervention) or bone graft (control), with a subepithelial connective tissue graft in both groups; outcome assessors and data analysts will be blinded. Patients will be followed for 6 months to evaluate buccal bone and soft tissue thickness, Pink Esthetic Score (PES), and implant survival.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients requiring immediate implant placement in the anterior maxilla - Adequate bone and soft tissue for implant placement. Exclusion criteria: Systemic conditions or medications affecting bone healing - Poor oral hygiene or uncontrolled periodontal disease - Smokers or patients with habits that may compromise implant success - Sites with acute infection or insufficient bone for implant placement.

Intervention groups
Intervention Group: Buccal gap filled with demineralized autogenous dentin graft after immediate implant placement, covered with a 1.5 mm subepithelial connective tissue graft from the palate. Control Group: Buccal gap filled with autogenous bone graft after immediate implant placement, covered with an identical 1.5 mm subepithelial connective tissue graft from the palate.

Main outcome variables
Buccal bone thickness; Soft tissue thickness; Pink Esthetic Score (PES); Implant survival

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110726007128N11**
Registration date: **2025-09-26, 1404/07/04**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-26, 1404/07/04**
Update count: **0**

Registration date
2025-09-26, 1404/07/04

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-23, 1404/07/01

Expected recruitment end date
2025-10-02, 1404/07/10

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison between autogenous tooth and autogenous bone graft for phenotype modification around immediate implants

Public title
Enhancing Dental Implants with Your Own Tooth or Bone: A Scientific Comparison
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adults aged ≥ 18 years Systemic condition suitable for oral surgery (ASA I or II) Healthy periodontium in adjacent teeth (no probing depth ≥ 4 mm and no bleeding on probing) indication for immediate implant placement in the anterior region for endodontic or restorative reasons Ability and willingness to attend follow-up visits and provide informed consent
Exclusion criteria:
Poor oral hygiene (high Plaque Index or inability to maintain oral hygiene) Active smoking (>10 cigarettes/day or ≥10 pack-years) Pregnancy or breastfeeding Severe periodontal disease Uncontrolled diabetes (HbA1c > 7.0%) History of head and neck radiotherapy Current or past use of bisphosphonates, denosumab, or long-term systemic corticosteroids/immunosuppressants alcohol or substance abuse Systemic or metabolic bone diseases interfering with healing Inadequate bone anatomy to achieve primary implant stability inability or unwillingness to attend follow-up visits Active infection at the extraction site (clinical signs of infection or purulence)
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, participants will be allocated in a 1:1 ratio using block randomization with a block size of 4 to assign them to either the intervention or control group. Randomization will be performed at the individual level. The random sequence will be generated using statistical software (SPSS Random Number Generator or Random Allocation Software). To ensure allocation concealment, sequentially numbered, opaque, sealed envelopes (SNOSE) will be used. These envelopes will be prepared and safeguarded by an independent colleague not involved in the research team. After obtaining informed consent and confirming eligibility criteria, the envelope corresponding to the patient's inclusion order will be opened to reveal the assigned intervention type.
Blinding (investigator's opinion)
Single blinded
Blinding description
Outcome Assessors a) Clinical Photograph Assessor (for Pink Esthetic Score - PES): Status: Blinded. Procedure: Standardized clinical photographs of the implant site will be taken at the 6-month follow-up. All photographs will be coded with a unique patient ID number that does not indicate the group allocation. A single, calibrated assessor, who is independent of the surgical team and has not been involved in the patient's care, will score all photographs using the PES index. This assessor will be explicitly blinded to the patient's group assignment. b) Radiographic Assessor (for Buccal Bone Thickness): Status: Blinded. Procedure: All Cone-Beam Computed Tomography (CBCT) scans taken pre-operatively and at 6 months will be analyzed using dedicated software. The scans will be de-identified and assigned random codes. A radiologist or a trained assessor, who is independent of the study and blinded to the group allocation and the time point (pre-op vs. 6-month), will measure the buccal bone thickness. The software screen will be set up to display only the coded image, hiding any patient or group identifiers. Data analyzer: Status: Blinded. Procedure: For the primary statistical analysis, the data file provided to the statistician will contain generic group labels (e.g., "Group A" and "Group B"). The identity of which group is the intervention (dentin graft) and which is the control (bone graft) will be concealed until after the analysis of all primary and secondary outcomes is complete and the results are finalized.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, Iran
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Tabriz
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Postal code
5165665931
Approval date
2025-01-27, 1403/11/08
Ethics committee reference number
IR.TBZMED.DENTISTRY.REC.1403.072

Health conditions studied

1

Description of health condition studied
Periodontal disease
ICD-10 code
K05.6
ICD-10 code description
Periodontal disease, unspecified

Primary outcomes

1

Description
Buccal bone thickness
Timepoint
Measuring buccal bone thickness at the beginning of the study (before the intervention) and 6 months after surgery
Method of measurement
Measured using cone-beam computed tomography

2

Description
Soft tissue thickness
Timepoint
Baseline (at implant placement)and 6 months after surgery
Method of measurement
Measured using a size 20 endodontic file with a silicone stop at 1 mm and 3 mm from the line connecting the marginal points of adjacent teeth

3

Description
Pink Esthetic Score
Timepoint
6 months after surgery, after placement of the implant prosthesis
Method of measurement
Assessed visually and scored according to the standard Pink Esthetic Score index

4

Description
Implant survival
Timepoint
6 months after surgery
Method of measurement
Evaluated clinically by recording implant mobility, infection, or loss

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After tooth extraction and site preparation, the implant is placed immediately in the anterior maxilla. The gap between the implant and the buccal socket wall is filled with a demineralized autogenous dentin graft prepared from the patient’s extracted tooth. A 1.5 millimeter thick subepithelial connective tissue graft is then harvested from the patient’s palate and placed over the implant and dentin graft, then sutured. All procedures are performed under local anesthesia. Preparation of the autogenous dentin graft: The extracted teeth are cleaned with ethyl alcohol, the root portions are collected and ground. The ground particles are placed in distilled water and hydrogen peroxide solution, then dehydrated in ethyl alcohol and ethyl ether, and finally partially demineralized in 2% nitric acid (HNO_3).
Category
Treatment - Surgery

2

Description
Control group: After tooth extraction and site preparation, the implant is placed immediately in the anterior maxilla. The gap between the implant and the buccal socket wall is filled with autogenous bone graft. A 1.5 millimeter thick subepithelial connective tissue graft is then harvested from the patient’s palate and placed over the implant and bone graft, then sutured. All procedures are performed under local anesthesia.The autogenous bone graft is harvested from the adjacent site of the surgical area using a bone scraper and shaped to fill the gap between the implant and the buccal socket wall
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz University of Medical Sciences, Faculty of Dentistry, Implant Department
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Tabriz University of Medical Sciences
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
Tabriz University of Medical Sciences
Full name of responsible person
Dr Adileh Shirmohamadi
Position
Periodontist/ professor
Latest degree
Specialist
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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