Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of dimensional changes in bone and soft tissue thickness using demineralized dentin graft and freeze-dried bone allograft for alveolar ridge preservation in maxillary -pre molar tooth sockets. Randomized clinical trial

Protocol summary

Study aim
Comparison of the Effects of Demineralized Dentin Graft and Freeze-Dried Bone Allograft on Bone Dimensional Changes and Soft Tissue Thickness in Alveolar Ridge Preservation

Design
A two-arm, parallel-group randomized clinical trial involving 16 patients, randomized using permuted block randomization with variable block sizes of 4 and 6.

Settings and conduct
This is a two-arm, parallel-group randomized clinical trial to be conducted at the School of Dentistry, Guilan University of Medical Sciences. Patients will be allocated to two groups for ARP: FDBA and DDG. In the DDG group, an extracted third molar will be used to prepare the graft material by grinding it with a hand-operated bone mill. The prepared graft will be placed in the extraction socket and covered with an absorbable collagen membrane. CBCT scans and soft tissue thickness measurements will be obtained before ARP and four months afterward. DIO implants will be placed four months after the intervention. The outcome assessor and data analyst will be blinded to treatment allocation.

Participants/Inclusion and exclusion criteria
Inclusion Criteria - Age ≥ 18 years. - Presence of a non-restorable maxillary premolar and a non-restorable maxillary third molar. - Extraction sockets with less than 50% buccal bone loss. Exclusion Criteria - Presence of acute or chronic infection or local pathology at the intended grafting site. - Presence of parafunctional habits. - Implant placement limitations - Use of medications that may interfere with bone healing - History of uncontrolled systemic diseases or conditions that may interfere with bone healing

Intervention groups
1. Demineralized Dentin Graft (DDG) Group 2. Freeze-Dried Bone Allograft (FDBA) Group

Main outcome variables
Reduction in alveolar ridge width (mm). Soft tissue thickness before ARP and four months after ARP. Need for additional interventions before implant placement.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221024056284N2**
Registration date: **2026-10-24, 1405/08/02**
Registration timing: **prospective**

Last update: **2026-10-24, 1405/08/02**
Update count: **0**

Registration date
2026-10-24, 1405/08/02

Registrant information

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Atiye Mirzaei

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-10-25, 1405/08/03

Expected recruitment end date
2026-11-07, 1405/08/16
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of dimensional changes in bone and soft tissue thickness using demineralized dentin graft and freeze-dried bone allograft for alveolar ridge preservation in maxillary -pre molar tooth sockets. Randomized clinical trial

Public title
Comparison of demineralized dentin graft and freeze-dried bone allograft for alveolar ridge preservation after tooth extraction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age ≥ 18 years Presence of a non-restorable maxillary premolar and a non-restorable maxillary third molar Extraction sockets with less than 50% buccal bone loss
Exclusion criteria:
Presence of acute or chronic infection or local pathology at the intended grafting site Presence of parafunctional habits Implant placement limitations, such as insufficient vertical bone height Use of medications that may interfere with bone healing, such as corticosteroids, hormone therapy, or bisphosphonates History of uncontrolled systemic diseases or conditions that may interfere with bone healing, including smoking, diabetes mellitus, immunosuppression, fibrous dysplasia, bleeding disorders, hyperparathyroidism, pregnancy, or a history of head and neck radiotherapy or chemotherapy within the previous five years
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **16**
Randomization (investigator's opinion)
Randomized
Randomization description
Random Sequence Generation: Treatment allocation will be performed in a 1:1 ratio using permuted block randomization with variable block sizes of 4 and 6 to minimize the predictability of the allocation sequence and reduce selection bias. Software and Independence of Sequence Generation: The randomization sequence will be generated by a biostatistician who is completely independent of treatment delivery, participant recruitment, surgery, and outcome assessment, using validated statistical software (R version 4.5 with the blockrand package or the online Sealed Envelope randomization service).
Blinding (investigator's opinion)
Double blinded
Blinding description
Due to the inherent physical differences between the preparation of autogenous dentin particles and the use of commercially packaged bone graft powder, blinding of the surgeon and participants is not feasible. Therefore, blinding will be implemented according to the roles of the individuals involved, in accordance with the CONSORT guidelines for non-pharmacological treatments. **Surgeon:** The operating surgeon will necessarily be aware of the type of graft material used and will therefore be unblinded. **Participant:** Participants will be aware of the treatment procedures and the collection of their extracted teeth; therefore, they will not be blinded. **Outcome Assessor Blinding:** Measurements of bone width and soft tissue thickness on cross-sectional CBCT images obtained at baseline and four months after the intervention will be performed by an independent oral and maxillofacial radiologist. All image files will be de-identified and provided to the radiologist without patient names, imaging time points, or treatment group information to ensure blinding. **Data Analyst Blinding:** The statistical analyst will receive the data using neutral group codes (e.g., Group A and Group B) and will remain unaware of the group identities until the statistical modeling and extraction of the final results have been completed.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Namjoo Street, Shahid Siadati Street, Opposite 17 Shahrivar Hospital, Rasht
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Postal code
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Approval date
2026-10-22, 1405/07/30

Ethics committee reference number
IR.GUMS.REC.1405.353

Health conditions studied

1

Description of health condition studied
Alveolar Ridge Preservation Following Maxillary Premolar Extraction
ICD-10 code
K08.2
ICD-10 code description
Atrophy of edentulous alveolar ridge

Primary outcomes

1

Description
Change in Alveolar Ridge Width
Timepoint
At baseline, before tooth extraction and alveolar ridge preservation, and four months after the intervention, before implant placement surgery.
Method of measurement
Alveolar ridge width will be measured on standardized cross-sectional cone-beam computed tomography images obtained at baseline and four months after the intervention. Measurements will be performed by an independent oral and maxillofacial radiologist blinded to group allocation. The change in ridge width will be calculated as the four-month measurement minus the baseline measurement.

Secondary outcomes

1

Description
Change in soft tissue thickness
Timepoint
At baseline, before tooth extraction and alveolar ridge preservation, and four months after alveolar ridge preservation, before the start of implant placement surgery.
Method of measurement
Soft tissue thickness at the alveolar ridge will be measured before tooth extraction and four months after alveolar ridge preservation, initially using an endodontic file and subsequently using a surgical gauge. Measurements will be recorded in millimeters.

2

Description
Need for additional bone grafting at the time of implant placement
Timepoint
Four months after alveolar ridge preservation, during implant placement surgery.
Method of measurement
The need for additional bone grafting following implant placement will be determined by the surgeon's clinical assessment of the bone thickness surrounding the implant and recorded as yes or no.

Intervention groups

1

Description
Intervention Group 1 (DDG Group): After obtaining the baseline CBCT scan for patients in the DDG group, patients will rinse their mouths with 0.12% chlorhexidine mouthwash for one minute. Local anesthesia will then be administered simultaneously to the designated premolar and third molar using 2% lidocaine with 1:80,000 epinephrine. Soft tissue thickness will subsequently be assessed using an endodontic file and a gauge. The third molar and premolar will be extracted with minimal trauma using a flapless technique with a periotome and surgical forceps (Nordent Manufacturing Inc., IL, USA). Following tooth extraction, granulation tissue will be thoroughly curetted from the extraction sockets, which will then be irrigated with normal saline. The integrity of the bony walls of the premolar socket will be assessed using a Williams probe (Nordent Manufacturing Inc.), and the transverse bone dimensions will be recorded using a gauge. In the DDG group, the extracted third molar will be used to prepare the graft material. For this purpose, the remaining periodontal ligament (PDL), cementum, soft tissue, and any carious lesions will be removed using a high-speed finishing bur under continuous irrigation with sterile saline. The pulp tissue will be removed using sterile endodontic files, and the tooth will be ground into fine particles using a hand-operated bone mill (Bone Mill, JUYA, Pakistan). The particles will then be immersed in 0.6 N hydrochloric acid for 30 minutes for demineralization. Subsequently, they will be rinsed twice with normal saline and dried using sterile gauze. Finally, the premolar socket will be densely filled with the prepared DDG particles. An absorbable collagen membrane (cenomembrane, Tissue Regeneration Corp., Kish Island, Iran), with a medium thickness of 0.6–0.9 mm, will be placed to cover the socket and graft material. The membrane will be secured using the open membrane approach and an internal crisscross knot with 4-0 monofilament nylon sutures (Supalon, Supa, Iran). After four months, a second CBCT scan will be obtained to assess dimensional changes in the alveolar ridge. At the second appointment, four months after grafting, second-stage surgery will be performed for implant placement. Patients will first rinse their mouths with 0.12% chlorhexidine mouthwash. Following local anesthesia with 2% lidocaine and 1:80,000 epinephrine at the designated site, soft tissue thickness will be measured. A full-thickness mucoperiosteal flap will then be elevated, and the clinical bone width will be measured again using a surgical gauge. Finally, in both groups, regular-diameter dental implants from the DIO implant system will be placed at the grafted sites according to the standard surgical protocol.
Category

Treatment - Surgery

2

Description

Intervention Group 2 (FDBA Group): After obtaining the baseline CBCT scan, patients in the FDBA group will rinse their mouths with 0.12% chlorhexidine mouthwash for one minute. Local anesthesia will then be administered to the designated premolar using 2% lidocaine with 1:80,000 epinephrine. Soft tissue thickness will subsequently be assessed using an endodontic file and a gauge. The designated premolar will then be extracted with minimal trauma using a flapless technique with a periotome and surgical forceps (Nordent Manufacturing Inc., IL, USA). Following tooth extraction, granulation tissue will be thoroughly curetted from the extraction socket, which will then be irrigated with normal saline. The extracted third molar will not be used as graft material in this group. The integrity of the socket walls will subsequently be assessed using a Williams probe (Nordent Manufacturing Inc.), and the transverse bone dimensions will be measured using a gauge. The extraction socket will be densely filled and reconstructed using FDBA (150–1000 µm, CenoBone®, Tissue Regeneration Corp., Kish Island, Iran). After the socket has been filled, the entrance to the grafted socket will be covered with an absorbable collagen membrane (Cenomembrane, Tissue Regeneration Corp., Kish Island, Iran), with a thickness of 0.6–0.9 mm, using the open membrane approach. The membrane will be secured with an internal crisscross suture using 4-0 monofilament nylon sutures (Supalon, Supa, Iran). Standard postoperative instructions, including antibiotic therapy, analgesics, and chlorhexidine mouthwash, will be provided to the patients. Sutures will be removed after 10–14 days. After four months, a second CBCT scan will be obtained to assess dimensional changes in the alveolar ridge. At the second appointment, four months after grafting, second-stage surgery will be performed for implant placement. Patients will first rinse their mouths with 0.12% chlorhexidine mouthwash. Following local anesthesia with 2% lidocaine and 1:80,000 epinephrine at the designated site, soft tissue thickness will be measured. A full-thickness mucoperiosteal flap will then be elevated, and the clinical bone width will be measured again using a surgical gauge. Finally, in both groups, regular-diameter dental implants from the DIO implant system will be placed at the grafted sites according to the standard surgical protocol.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontology, School of Dentistry, Guilan University of Medical Sciences

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

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Ashkan Salari

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
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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
Individual participant data will not be shared publicly due to participant confidentiality and privacy considerations. No additional information is 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