Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative Efficacy of Hyaluronic Acid-Enriched Allograft for Alveolar Ridge Preservation in Multiple Adjacent Extraction Sites: A Randomized Controlled Trial

Protocol summary

Study aim

To compare the efficacy of hyaluronic acid-enriched allograft versus natural healing (no intervention) for alveolar ridge preservation following extraction of multiple adjacent teeth.

Design

Two-arm parallel group single-blind randomized controlled trial with blinded outcome assessment. Stratified block randomization (buccal bone thickness: <1mm vs ≥1mm, block size 2) using Excel, allocation concealed by SNOSE. 24 patients, single-center.

Settings and conduct

This single-center study will be conducted at the Department of Periodontology, School of Dentistry, Tehran University of Medical Sciences. Following tooth extraction, patients will be assigned to either the allograft+HA group or the control group (natural healing). A 3-month follow-up will be performed using CBCT and digital scans. The outcome assessor and data analyst will be blinded to group allocation through coding of images and data.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1-Need for extraction of 2 or 3 adjacent teeth (right second premolar to left second premolar) 2-Age ≥ 18 years 3-No systemic diseases affecting bone healing (uncontrolled diabetes, severe osteoporosis) 4-No medications affecting bone healing (bisphosphonates) 5-No acute periapical infection or fistula 6-Socket with buccal dehiscence < 50% after extraction Exclusion Criteria: 1-Non-compliance with treatment instructions 2-Withdrawal for personal or medical reasons 3-Smoking 4-Poor oral hygiene or non-cooperation 5-Vulnerable groups (pregnant women, unable to provide informed consent)

Intervention groups

Group 1 (Intervention - A+H): Socket filled with allograft + hyaluronic acid Group 2 (Control - C): Natural healing

Main outcome variables

Changes in buccolingual alveolar ridge width at 1, 2, 3, 4, and 5 mm apical to the CEJ; changes in apicocoronal height of the buccal and lingual/palatal crest; volumetric soft tissue changes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260216068884N1**
Registration date: **2026-03-15, 1404/12/24**
Registration timing: **registered_while_recruiting**

Last update: **2026-03-15, 1404/12/24**
Update count: **0**

Registration date

2026-03-15, 1404/12/24

Registrant information

Name

Ghazal Soleimani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-03-06, 1404/12/15

Expected recruitment end date

2026-08-06, 1405/05/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative Efficacy of Hyaluronic Acid-Enriched Allograft for Alveolar Ridge Preservation in Multiple Adjacent Extraction Sites: A Randomized Controlled Trial

Public title
Comparison of two methods for preserving jawbone after the extraction of several adjacent teeth
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients requiring the extraction of multiple adjacent teeth (two or three teeth, from the right second premolar to the left second premolar region). Aged at least 18 years. Absence of severe systemic diseases that may affect bone healing (e.g., uncontrolled diabetes, severe osteoporosis). No use of medications that affect bone healing (e.g., bisphosphonates). Absence of acute periapical infection or fistula in the teeth to be extracted. Sockets with less than 50% buccal bone dehiscence after tooth extraction.
Exclusion criteria:
Patients who do not comply with treatment instructions during the study. Patients who withdraw from the study for personal or medical reasons Smokers. Patients with poor oral hygiene or unwillingness to follow hygiene instructions. Individuals belonging to vulnerable groups, including pregnant women or those lacking legal capacity or mental ability to provide informed consent.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Following tooth extraction and initial measurement of buccal bone thickness using a caliper, patients will be stratified into two distinct strata based on the baseline buccal bone thickness in the study area: Stratum I: Buccal bone thickness < 1 mm Stratum II: Buccal bone thickness ≥ 1 mm Within each stratum, a balanced block randomization list with block sizes of 2 (allocating one patient to each of the two groups, A+H and C, per block) will be generated by the study statistician, who is not involved in the patient selection or treatment process, using the random number generation function in Excel software. The final allocation sequence for each stratum will be recorded confidentially as "patient number → treatment group." To ensure allocation concealment, the randomization sequence for each stratum will be placed in sequentially numbered, opaque, sealed envelopes (SNOSE). Each envelope will be identified solely by a sequential number and will be opened by the surgeon in the order of eligible patient enrollment within the corresponding stratum. The treatment team will remain unaware of the assigned group (A+H or C) until the moment the envelope is opened, and allocation will only occur after completion of baseline assessments and confirmation of eligibility criteria. The statistical analyst will remain blinded to group assignments through the use of coded labels (e.g., Code 1 and Code 2) that bear no relation to the nature of the interventions, ensuring blinded data analysis.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is designed as a single-blind randomized controlled trial. Due to the nature of the surgical intervention, the surgeon (care provider) cannot be blinded to group allocation. However, the following individuals are blinded: Participants: Patients are not informed of their group assignment (intervention group receiving hyaluronic acid-enriched allograft or control group with natural healing). This is achieved by using identical postoperative care instructions and not disclosing the specific treatment received. Outcome assessors: All outcome evaluations, including CBCT image analysis and soft tissue contour assessments, are performed by independent evaluators (radiologists and clinicians) who are unaware of the treatment allocation. Blinding is maintained by coding all images and digital models with participant numbers only, without any indication of group assignment. Data analyst: The statistical analyst receives a fully coded dataset (e.g., Code 1 and Code 2 representing the groups) with no reference to the actual interventions, ensuring blinded data analysis. The principal investigator is involved in the surgical procedure and, therefore, is not blinded to the results. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes (SNOSE), which were opened only after confirmation of eligibility criteria and completion of baseline assessments. This blinding methodology is considered adequate to minimize detection and performance bias.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences, School of Dentistry

Street address
TUMS School of Dentistry, North Kargar St., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
14399-55934

Approval date
2026-02-22, 1404/12/03

Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1404.114

Health conditions studied

1

Description of health condition studied
Tooth extraction of multiple adjacent teeth and subsequent alveolar bone resorption

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Changes in alveolar ridge dimensions (width and height) measured by CBCT

Timepoint
Baseline (before extraction) and 3 months after extraction

Method of measurement
Cone Beam Computed Tomography (CBCT) with image superimposition and analysis using Romexis software

Secondary outcomes

1

Description
Changes in soft tissue contour (volume) of the alveolar ridge

Timepoint
Baseline (before extraction) and 3 months after extraction

Method of measurement
Digital scanning and superimposition of STL files using analysis software

2

Description
Postoperative pain intensity

Timepoint
Daily for the first week after extraction

Method of measurement
Visual Analogue Scale (VAS) from 0 to 10

Intervention groups

1

Description
Intervention group: Allograft enriched with Hyaluronic Acid: After tooth extraction, the socket will be filled with a mixture of allograft particles and hyaluronic acid solution (Perfectha) at a 1:10 ratio. A collagen cone (Collacone) will be placed over the graft and secured with non-absorbable sutures.

Category
Treatment - Surgery

2

Description
Control group: Natural healing (no graft): After tooth extraction, the socket will be left to heal naturally with blood clot formation. No bone graft or hyaluronic acid will be placed in the socket.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Dentistry, Tehran University of Medical Sciences

Full name of responsible person
Ghazal Soleimani

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2

Recruitment center

Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
Ramin kordi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Self-funded by researcher

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ghazal Soleimani

Position
Postgraduate student (Resident)

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Deidentified Individual Participant Data Set (IPD), Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, Analytic Code, and Data Dictionary

When the data will become available and for how long

Starting 6 months after publication of the main results and available for 5 years

To whom data/document is available

Available to researchers working in academic institutions who provide a methodologically sound proposal

Under which criteria data/document could be used

For non-commercial research purposes only, with proper citation of the original study. The study principal investigator and the institutional ethics committee must approve proposals. Data should only be used for the approved research purpose and cannot be redistributed.

From where data/document is obtainable

Available through the IRCT website (www.irct.ir) and upon request from the corresponding author at ghazal.soleimani73@gmail.com

What processes are involved for a request to access data/document

1. Submit a formal request email including a research proposal and intended use of data. 2. Review by study team (1-2 weeks). 3. Sign data sharing agreement. 4. Data delivery (1-2 weeks after agreement). Total: 3-5 weeks.

Comments