Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Radiographic study of simultaneous use of atorvastatin and collagen foam in dentate gingival recession on CBCT images.

Protocol summary

Study aim

Radiographically evaluate the effect of the combined application of atorvastatin and collagen foam on alveolar bone healing following tooth extraction, using cone-beam computed tomography (CBCT) images, and to compare the outcomes with those of collagen foam alone.

Design

A phase II randomized, double-blind, parallel-group, controlled clinical trial will be conducted on 17 patients requiring tooth extraction. Participants will be randomly allocated into intervention and control groups using the RAND function in Microsoft Excel.

Settings and conduct

This study will be conducted at the Department of Oral and Maxillofacial Surgery, Tehran Azad Dental University, and bone healing after tooth extraction will be evaluated by CBCT after 3 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria :Adult patients 18 years of age or older stable periodontal status and good oral hygiene. Ability and willingness to comply with study requirements, including attendance at follow-up sessions up to 3 months after the intervention. Signing a written informed consent form prior to study entry. exclusion criteria : Presence of active local or systemic infection or inflammation. Presence of systemic or local diseases that may interfere with bone healing, including but not limited to uncontrolled diabetes mellitus (HbA1c >7%), osteoporosis, and hyperparathyroidism. Current use or history of medications that interfere with bone repair Chronic use of corticosteroids

Intervention groups

following tooth extraction and socket debridement, collagen foam impregnated with atorvastatin will be placed into the extraction socket. Control group: following tooth extraction and socket debridement, only sterile absorbable collagen foam without atorvastatin will be placed in socket.

Main outcome variables

The outcome variable of this study is the radiographic bone healing of the extraction socket

General information

Reason for update

Acronym

ACB-Heal Trial

IRCT registration information

IRCT registration number: **IRCT20260427069191N1**
Registration date: **2026-05-05, 1405/02/15**
Registration timing: **prospective**

Last update: **2026-05-05, 1405/02/15**
Update count: **0**

Registration date

2026-05-05, 1405/02/15

Registrant information

Name

aida nazarzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-15, 1405/02/25

Expected recruitment end date

2026-08-16, 1405/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Radiographic study of simultaneous use of atorvastatin and collagen foam in dentate gingival recession on CBCT images.

Public title

Evaluation of the Combined Effect of Atorvastatin and Collagen Foam on Bone Healing After Tooth Extraction Using CBCT Images

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults aged 18 years or older requiring extraction of at least two teeth and subsequent bone regeneration procedures in the extraction sites. Patients with stable periodontal status and good oral hygiene Ability and willingness to comply with study requirements, including attendance at scheduled follow-up visits for up to 3 months. Provision of written informed consent prior to participation.

Exclusion criteria:

Presence of active local or systemic infection/inflammation. Presence of systemic or local diseases that may interfere with bone healing, including but not limited to uncontrolled diabetes mellitus (HbA1c >7%), osteoporosis, and hyperparathyroidism. Current or previous use of medications known to interfere with bone healing Chronic corticosteroid therapy. Known allergy or hypersensitivity to bone graft materials, collagen foam, or atorvastatin.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **17**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly allocated to the study groups using a computer-generated randomization sequence. In cases where a split-mouth design is used, the allocation of each extraction socket to either the intervention or control group will be determined by computer-generated randomization. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes (SNOSE) prepared by an independent researcher not involved in treatment or outcome assessment.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be conducted as a double-blind randomized clinical trial. The participants and the radiographic evaluator/statistical analyst will be blinded to the treatment allocation. The surgeon performing the intervention will not be blinded due to the nature of the procedure. The materials used in both groups will be prepared in identical containers and coded by an independent researcher who is not involved in treatment or outcome assessment. The allocation code will remain concealed until completion of data analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University, Tehran Medical Branch

Street address

Dr. Shariati St

City

Tehran

Province

Tehran

Postal code

1941933111

Approval date

2025-09-14, 1404/06/23

Ethics committee reference number

IR.IAU.DENTAL.REC.1404.066

Health conditions studied

1

Description of health condition studied

The health condition studied is alveolar bone defect/healing after tooth extraction. Tooth extraction leads to physiological bone resorption and delayed bone regeneration in the extraction socket, which may affect future prosthetic or implant treatment outcomes.

ICD-10 code

K05.31

ICD-10 code description

Chronic periodontitis, localized

Primary outcomes

1

Description
Radiographic bone healing of the extraction socket will be assessed using CBCT imaging by measuring bone density and bone fill percentage at 3 months after the intervention.
Timepoint
Three months after the intervention.
Method of measurement
The outcome will be measured using cone-beam computed tomography (CBCT) images to assess bone density and bone fill percentage in the extraction socket.

Secondary outcomes

empty

Intervention groups

1

Description
Participants allocated to the intervention group will receive local alveolar ridge preservation treatment immediately after tooth extraction using a sterile absorbable collagen foam scaffold impregnated with atorvastatin. The collagen foam will serve as a biocompatible carrier for the localized delivery of atorvastatin into the extraction socket. Following atraumatic tooth extraction and socket debridement, the atorvastatin-loaded collagen foam will be placed into the socket to fill the defect adequately. The site may then be sutured if necessary to stabilize the material and promote healing.Atorvastatin is used due to its potential osteogenic, angiogenic, and anti-inflammatory effects, which may enhance bone regeneration and reduce post-extraction alveolar bone resorption. The collagen foam is selected as a biodegradable scaffold to support clot stabilization and gradual release of the active agent during the healing period.Participants will be followed clinically and radiographically during the postoperative healing period, with assessments performed at predefined follow-up 3 months after intervention) to evaluate bone preservation and regeneration outcomes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farhikhtegan hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Islamic Azad University
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Associate professor
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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Individual data of participants after removal of identifying information (De-identified data), including data related to the main outcome of the study (bone density and percentage of bone filling in CBCT images), will be shared upon reasonable request of the researchers and after the publication of the study results.
When the data will become available and for how long
Access begins 3 months after results are published.
To whom data/document is available
Researchers working at academic institutions
Under which criteria data/document could be used
The data/document may be used exclusively for academic and scientific research purposes
From where data/document is obtainable
The data and source documents are obtainable from the , Islamic Azad University, Tehran Medical Sciences dental Branch.
What processes are involved for a request to access data/document
Access to the data and documents of this study requires the submission of an official research request and obtaining approval from the Research and Technology Deputy of Islamic Azad University, Tehran Medical Sciences Branch, as well as the Research Ethics Committee. After the research proposal is approved and an ethics permit is issued, access to the data will only be possible for members of the research team and within the framework of the approved study objectives. All data will be provided to researchers in an anonymized form before use in research, and their use is limited to the approved scientific and research purposes. Any use outside the scope of the study requires obtaining additional permissions.

Comments