Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Design and evaluation of an alendronate-loaded chitosan membrane for bone regeneration in dental procedures, double-blind Randomized clinical trial

Protocol summary

Study aim
Fabrication and evaluation of alendronate-loaded chitosan nanofibers.

Design
This study is a Phase II randomized, double-blind, controlled clinical trial with parallel groups, conducted on 20 patients.

Settings and conduct
This study involves periodontal surgery and will be conducted at the Dental School of the Islamic Azad university Khorasgan.

Participants/Inclusion and exclusion criteria
Inclusion criteria were as follows: age between 25 and 55 years; good general health (ASA physical status I or II according to the American Society of Anesthesiologists [ASA] classification); no use of medications affecting bone healing (e.g., bisphosphonates or corticosteroids); no antibiotic use within the previous 3 months; non-smokers or individuals smoking fewer than five cigarettes per day; availability of a preoperative cone-beam computed tomography (CBCT) scan suitable for evaluating the location of intrabony defects; and the presence of two intrabony periodontal defects with a probing depth of ≥ 5 mm and similar morphology. Exclusion criteria included a history of periodontal treatment within the previous 6 months, pregnancy or lactation, uncontrolled systemic diseases, active infection at the surgical site

Intervention groups
The study consisted of two intervention groups. The treatment group received the fabricated collagen nanofibers loaded with alendronate, whereas the placebo group received collagen nanofibers with identical physical and structural characteristics but without alendronate.

Main outcome variables
Probing Pocket Depth (PPD/PD) ; Clinical Attachment Level (CAL) ; Bleeding on Probing (BOP) ; Change in Bone Height

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210118050067N3**
Registration date: **2026-09-13, 1405/06/22**
Registration timing: **prospective**

Last update: **2026-09-13, 1405/06/22**
Update count: **0**

Registration date
2026-09-13, 1405/06/22

Registrant information
Name
Erfaneh Ghassami
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 3792 7118
Email address
e.ghassami@pharm.mui.ac.ir

Recruitment status
Not yet recruiting
Funding source

Expected recruitment start date
2027-04-21, 1406/02/01
Expected recruitment end date
2027-10-23, 1406/08/01
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design and evaluation of an alendronate-loaded chitosan membrane for bone regeneration in dental procedures, double-blind Randomized clinical trial

Public title

Design and evaluation of an alendronate-loaded chitosan membrane for bone regeneration in dental procedures, double-blind Randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 25 and 55 years. Good general health status (ASA I or ASA II) according to the American Society of Anesthesiologists (ASA) classification criteria No use of medications affecting bone healing (e.g., bisphosphonates or corticosteroids) No antibiotic use within the past three months.5. Non-smoker or smoking fewer than 5 cigarettes per day Non-smoker or smoking fewer than 5 cigarettes per day Availability of an appropriate pre-treatment CBCT scan for evaluation of the location of bone defects. Presence of two intrabony periodontal defects with a depth of ≥ 5 mm and similar morphology.

Exclusion criteria:

Receipt of periodontal treatment within the previous 6 months. Pregnancy or lactation Uncontrolled systemic diseases. Active infection at the surgical site

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is designed as a randomized, double-blind, split-mouth clinical trial. In each participant, two comparable sites (the right and left sides of the jaw or two anatomically similar intrabony periodontal defects) will be selected. One site will be randomly assigned to the test group, while the contralateral site will be assigned to the control group.Randomization will be performed at the site level rather than at the participant level. A computer-generated randomization sequence will be created using a randomization website or software. In this study, Randomized.org will be used for randomization. For each participant, the left and right treatment sites will be randomly allocated to either the treatment or placebo group. Thus, the participants themselves will not be randomized; rather, the treatment site (left or right side of the mouth) within each participant will be randomized.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is designed as a randomized, split-mouth clinical trial. In each participant, two comparable sites (the right and left sides of the jaw or two anatomically similar intrabony periodontal defects) will be selected. One site will be randomly assigned to the test group, while the contralateral site will be assigned to the control group. Blinding will be implemented as follows. A third party who is not involved in the study (a dental assistant) will be responsible for maintaining the randomization schedule. According to the allocation list, the dental assistant will provide the treating clinician with either the alendronate-loaded collagen nanofiber or the placebo nanofiber. The two materials will be identical in appearance and therefore indistinguishable. The treating clinician, who is aware of the treatment allocation, will apply the assigned material to the corresponding treatment site. Subsequently, all clinical and radiographic data will be collected and analyzed by an independent outcome assessor (analyst), who may be a dental assistant and who is blinded to the treatment allocation and the study groups. The participants will also remain unaware of the treatment assigned to each site. Therefore, the participants and the outcome assessor will be blinded to the allocation, whereas the treating clinician will not be blinded and will be aware of the treatment assignment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2026-06-09, 1405/03/19

Ethics committee reference number

IR.MUI.PHANUT.REC.1405.049

Health conditions studied

1

Description of health condition studied
Bone regeneration in dental procedures
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Measurement of probing pocket depth (PPD)
Timepoint
Before the intervention and at 1, 3, and 6 months post-intervention
Method of measurement
Dental radiography

2

Description
Clinical Attachment Level (CAL)
Timepoint
Before the intervention and at 1, 3, and 6 months post-intervention
Method of measurement
Dental radiography

3

Description
Bleeding on Probing (BOP)
Timepoint
At the time of intervention
Method of measurement
Clinical assessment

4

Description
Change in Bone Height
Timepoint
Before the intervention and at 1, 3, and 6 months post-intervention
Method of measurement
Dental radiography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:The patient was comfortably seated in the dental chair and was instructed to rinse the mouth with 10 mL of 0.2% chlorhexidine digluconate solution. The surgical site was anesthetized using 2% lidocaine with epinephrine. Intrasulcular and interdental incisions were made on the buccal and lingual aspects using No. 12 and No. 15 periodontal blades, respectively. A full-thickness mucoperiosteal flap was carefully elevated, with particular attention paid to preserving the interdental papillary tissue as much as possible.After flap reflection and exposure of the osseous defects, thorough root planing was performed. The osseous defects were debrided using curettes, and the surgical site was thoroughly irrigated with normal saline. Subsequently, the bone graft material was applied to the defect area.In the test group, a chitosan nanofibrous membrane containing hydroxyapatite (HA), tricalcium phosphate (TCP), and alendronate was used. HA and TCP were incorporated at a ratio of 30:70, respectively, and alendronate was incorporated at a concentration of 10% w/w.Finally, the flap was repositioned without tension and sutured using a standard technique. The patients were instructed to rinse their mouths twice daily with 0.2% chlorhexidine digluconate mouthwash for 2 weeks. Postoperative instructions included avoiding hot foods, avoiding tooth brushing over the surgical dressing/site, and avoiding excessive or frequent mouth rinsing. Patients were also instructed to contact the clinic if any other problems or complications occurred.One week after surgery, the patients were recalled for suture removal and assessment of postoperative signs and symptoms. They were then instructed to continue chlorhexidine mouth rinsing for an additional week. Follow-up visits were scheduled at 2 weeks and at 1, 2, 3, and 6 months after surgery.At each follow-up visit, oral hygiene instructions were reinforced, and supragingival plaque was removed from the surgical sites. At 3 and 6 months postoperatively, the patients underwent clinical and radiographic evaluations of the test and control sites.
Category
Treatment - Drugs

2

Description
Control group:The patient was comfortably seated in the dental chair and was instructed to rinse the mouth with 10 mL of 0.2% chlorhexidine digluconate solution. The surgical site was anesthetized using 2% lidocaine with epinephrine. Intrasulcular and interdental incisions were made on the buccal and lingual aspects using No. 12 and No. 15 scalpel blades, respectively. A full-thickness mucoperiosteal flap was elevated, with care taken to preserve the interdental papillary tissue as much as possible.After flap reflection and exposure of the osseous defects, thorough root planing was performed. The osseous defects were debrided using curettes, and the surgical site was thoroughly irrigated with normal saline. Subsequently, bone graft material was applied to the defect area. In the control group, a similar chitosan nanofibrous membrane without the drug was used.Finally, the flap was repositioned without tension and sutured using a standard technique. The patients

were instructed to rinse their mouths twice daily with 0.2% chlorhexidine digluconate mouthwash for 2 weeks. Postoperative instructions included avoiding hot foods, avoiding tooth brushing over the surgical dressing, and avoiding excessive or frequent mouth rinsing. The patients were also instructed to contact the clinic if any other problems or complications occurred.One week after surgery, the patients were recalled for suture removal and assessment of postoperative signs and symptoms. They were then instructed to continue chlorhexidine mouth rinsing for an additional week. Follow-up visits were scheduled at 2 weeks and at 1, 2, 3, and 6 months after surgery.At each follow-up visit, oral hygiene instructions were reinforced, and supragingival plaque was removed from the surgical sites. At 3 and 6 months postoperatively, the patients underwent clinical and radiographic evaluations of the test and control sites.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Dentistry, Islamic Azad University, Khorasgan Branch, Isfahan, Iran

Full name of responsible person
Dr Ehsan rafii

Street address
Imam Reza Boulevard, Morvarid Street, between Valiasr Boulevard and Dr. Ahmad Ali Foroughi Street, Arghavaniyeh District, Islamic Azad University, Isfahan (Khorasgan) Branch, Isfahan, Iran.

City
Isfahan

Province
Isfehan

Postal code
8155139998

Phone
+98 913 318 2508

Email
ehsanrafiei@iau.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr Erfaneh Ghassami

Street address
Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran.

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 31 3668 0048

Email
e.ghassami@pharm.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Esfahan 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
School of Dentistry, Islamic Azad University, Isfahan (Khorasgan) Branch, Isfahan, Iran

Full name of responsible person
Dr Prisa Ranjbarian

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
School of Dentistry, Islamic Azad University, Isfahan (Khorasgan) Branch, Imam Reza Boulevard, Morvarid Street, between Valiasr Boulevard and Dr. Ahmad Ali Foroughi Street, Arghavaniyeh District, Isfahan, Iran.

City
Isfahan

Province
Isfehan

Postal code
8155139998

Phone
+98 31 3535 0019

Email
p.ranjbarian@iau.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr Parisa ranjbarian
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
School of Dentistry, Islamic Azad University, Isfahan (Khorasgan) Branch, Imam Reza Boulevard, Morvarid Street, between Valiasr Boulevard and Dr. Ahmad Ali Foroughi Street, Arghavaniyeh District, Isfahan, Iran.
City
Isfahan
Province
Isfehan
Postal code
8155139998
Phone
+98 31 3535 0019
Email
p.ranjbarian@iau.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr Parisa Ranjbarian
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
School of Dentistry, Islamic Azad University, Isfahan (Khorasgan) Branch, Imam Reza Boulevard, Morvarid Street, between Valiasr Boulevard and Dr. Ahmad Ali Foroughi Street, Arghavaniyeh District, Isfahan, Iran.
City
Isfahan
Province
Isfehan
Postal code
8155139998
Phone
+98 31 3535 0019
Email
p.ranjbarian@iau.ac.ir

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
Protection of patient privacy
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The study protocol and the statistical analysis plan will be detailed in the final manuscript
When the data will become available and for how long
At all times
To whom data/document is available
everyone
Under which criteria data/document could be used
The intellectual property rights associated with the study data are owned by the research team. Any use, reproduction, or publication of these data is permitted only with proper acknowledgment and citation of the original source.
From where data/document is obtainable
Refer to the article
What processes are involved for a request to access data/document
Email to the corresponding author
Comments