Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Studying the effect of using autologous dentin particles on maintaining tooth sockets in patients referring to Hamedan Dental School

Protocol summary

Study aim
To determine and compare the effect of using autologous dentin graft particles with the socket preservation method on the changes in bone dimensions (height and width) after extraction of maxillary premolar teeth in patients referred to Hamedan Dental School.

Design
Randomized, two-group, parallel group (allocation ratio 1:1), single-blind (outcome assessor), interventional, intraoral clinical trial. Patients are divided into control group (collagen membrane) and study group (autologous dentin + collagen membrane) by simple or block randomization.

Settings and conduct
After consent, patients are randomly divided into two groups in a 1:1 ratio. The premolar tooth is extracted atraumatically; then, in the study group, a socket with autologous dentin particles and collagen membrane is placed, and in the control group, only collagen membrane is placed. Both groups are sutured. Bone dimensions (width and height) are evaluated and compared with CBCT before surgery and 4 months later, using specialized software."

Participants/Inclusion and exclusion criteria
Inclusion criteria: Presence of an unretainable maxillary premolar tooth - the tooth cannot be treated or restored prosthetically, restoratively or periodontally. Exclusion criteria: Presence of inflammation or active infection (Acute Infection) in the area of the tooth in question (so that it prevents the standard restoration process). Presence of bleeding disorders or use of anticoagulant medications.

Intervention groups
Study group: Use of autologous dentin particles + collagen membrane. Control group: Use of collagen membrane alone (without graft material)."

Main outcome variables
Changes in alveolar bone height Changes in alveolar bone width

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251118068036N5**
Registration date: **2026-06-11, 1405/03/21**
Registration timing: **prospective**

Last update: **2026-06-11, 1405/03/21**
Update count: **0**

Registration date
2026-06-11, 1405/03/21

Registrant information

Name
omid ghorbani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-07-04, 1405/04/13

Expected recruitment end date
2028-02-02, 1406/11/13

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Studying the effect of using autologous dentin particles on maintaining tooth sockets in patients referring to Hamedan Dental School

Public title

Studying the effect of using patient dentin particles in preserving bone at the site of tooth extraction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of unmaintainable maxillary premolar teeth The area in question does not have an active infection. The patient is willing to participate in the study and sign an informed consent form.

Exclusion criteria:

The presence of inflammation or active infection (Acute Infection) in the area of the tooth in question (so that it prevents the standard restoration process). Presence of bleeding disorders or use of anticoagulant medications: which may make minimally invasive surgery difficult.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **18**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of eligible individuals to the study and control groups is done randomly using equal-sized random blocks. The allocation sequence is prepared by someone outside the treatment and surgical team and placed in sealed, opaque, numbered envelopes. After entering and recording the patient's initial information and before performing the intervention, the relevant envelope is opened and the patient's group is determined.

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome assessor, who is responsible for reviewing and measuring the CBCT images before the intervention and at the 4-month follow-up, will not be aware of the allocation of patients to the study or control group. The CBCT images will be provided to him/her in a coded form without mentioning the group name. Due to the nature of the intervention, blinding of the patient and surgeon is not possible.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Hamadan University of Medical Sciences

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Shahid Fahmideh St

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Province

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Postal code

6517838678

Approval date

2026-02-14, 1404/11/25

Ethics committee reference number

IR.UMSHA.REC.1404.957

Health conditions studied

1

Description of health condition studied

Maintaining tooth mobility after tooth extraction

ICD-10 code

Z48.8

ICD-10 code description

Encounter for other specified postprocedural aftercare

Primary outcomes

1

Description

The extent of changes in alveolar bone dimensions (bone height and width)

Timepoint

Time 1 (Baseline): Just before tooth extraction surgery (initial evaluation stage with CBCT). Time 2 (Follow-up): 4 months after tooth extraction surgery and intervention (final evaluation stage with CBCT).

Method of measurement

Measurement method:1. Obtaining CBCT (Cone Beam Computed Tomography) images of the desired area in two stages (before tooth extraction and 4 months after).2. Transferring images to specialized software (such as OnDemand3D or Romexis).3. Accurate measurement of bone height (distance from bone crest to the socket floor or specific landmark points) and bone width (at specific millimeter distances from the crest).4. Comparison of data obtained at two time points by the outcome assessor (who is unaware of the type of intervention/grouping - Single-blind) to calculate the percentage of dimensional changes.

Secondary outcomes

1

Description
Changes in the width of the alveolar bone at the site of tooth loss
Timepoint
Baseline: Before tooth extraction and intervention, with CBCTFollow-up: 4 months after surgery and intervention, with CBCT
Method of measurement
Bone width is measured in CBCT at a standard location and at predetermined sections. The pre- and post-intervention images are analyzed by dental radiology software and the distance between the buccal and palatal/lingual walls is recorded at specific areas. The amount of change in bone width between the two times is then compared.

Intervention groups

1

Description
Intervention group: In this group, after local anesthesia with 2% lidocaine, the maxillary premolar tooth is extracted using a minimally invasive method (atraumatic extraction) with the help of a periotome and fine elevators to preserve the integrity of the socket bone walls. Then, after washing with normal saline, the socket is covered with a collagen membrane (manufactured by Iranian Tissue Products Company). Finally, the edges of the membrane are fixed with non-continuous sutures (Figure of eight) using 4-0 Vicryl thread (Supa Company).
Category
Treatment - Surgery

2

Description
Control group: "In this group, after local anesthesia, the maxillary premolar tooth is extracted using an atraumatic extraction method with minimal damage to the socket bone walls. After cleaning the socket of granulation soft tissues with a surgical curette and rinsing with normal saline, the tooth socket remains empty. Then, to protect the blood clot and prevent soft tissue growth into the socket, the socket opening is covered with a resorbable collagen membrane and the edges of the membrane are fixed using non-continuous (Figure-of-eight) sutures with 4-0 thread. The patient undergoes the same postoperative care protocol after surgery."
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Hamadan 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
Hamedan 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
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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