Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative Evaluation of Soft Tissue Healing at Molar and Premolar Socket During Two-Stage Immediate Implant Placement Using Collagen Sponge versus Acellular Dermal Matrix (ADM): A Clinical Trial study

Protocol summary

Study aim

The primary objective of this study is to compare the effects of a collagen sponge and an acellular dermal matrix(ADM)on soft tissue healing outcomes following immediate implant placement

Design

A randomized, single-blinded, parallel-group clinical trial with two intervention groups, on 40 patients. Randomization will be performed using Randomizer.org

Settings and conduct

Patients requiring tooth extraction and immediate implant placement who present to the Mashhad School of Dentistry during the study period and meet the eligibility criteria will be enrolled in the study. Participants will be randomly assigned to intervention Groups using a block randomization. Outcome assessor and the data analyst will remain unaware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: adults(18 years older and older) with good general health, good oral hygiene, at least 5mm of bone for primary stability, Indication for molar extraction with immediate implant placement

Intervention groups

"Intervention Group 1": After tooth extraction and socket preparation, an immediate implant will be placed in the fresh socket during the same treatment session. The socket entrance will be covered with an absorbable collagen matrix. This material after hydration, will be placed over the socket entrance and fixed with sutures. "Intervention Group 2": After tooth extraction and socket preparation, an immediate implant will be placed in the fresh socket during the same treatment session. The socket entrance will be covered with an Acellular Dermal Matrix (ADM). ADM will be placed over the socket entrance after hydration and fixed with sutures. In both groups, surgery will be performed by a single surgeon, and the surgical protocol, medication regimen, and postoperative care will be identical

Main outcome variables

Degree of socket epithelialization(percentage)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260308068974N1**
Registration date: **2026-07-24, 1405/05/02**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-24, 1405/05/02**
Update count: **0**

Registration date

2026-07-24, 1405/05/02

Registrant information

Name

seyedsaeid Mahdizadeh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-05, 1405/03/15

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 Evaluation of Soft Tissue Healing at Molar and Premolar Socket During Two-Stage Immediate Implant Placement Using Collagen Sponge versus Acellular Dermal Matrix (ADM): A Clinical Trial study

Public title

Comparison of two barrier membranes for extraction socket tissue regeneration

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Good general health Good oral hygiene Need for molar tooth extraction with an indication for immediate implant placement in a fresh socket Presence of at least 5 mm of available bone to achieve primary implant stability

Exclusion criteria:

Smoking Systemic and Metabolic Diseases History of Chemotherapy or Radiotherapy Pregnancy Recent Use of Antibiotics or Corticosteroids Use of Medications Affecting Bone Metabolism

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly allocated to the two study groups using a permuted block randomization method. The randomization sequence will be generated using Randomization.org. Given that there are two study groups, a block size of four will be used, with the possible allocation sequences being AABB, ABAB, ABBA, BAAB, BABA, and BBAA. An independent researcher who is not involved in patient treatment or outcome assessment will generate and maintain the randomization sequence. To ensure allocation concealment, the assigned group for each participant will be placed in sequentially numbered opaque sealed envelopes (SNOSE). After a participant has been enrolled in the study and immediately before surgery, the corresponding envelope will be provided to the surgeon by the operating room nurse and opened at that time. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes prepared by an independent researcher. The envelopes will be opened only after participant enrollment and immediately before surgery. The surgeon will receive the allocation information at the time of intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be conducted using a single-blind design. Due to the nature of the surgical interventions, blinding of the surgeon will not be feasible. Participants will be informed about the treatment they receive as part of the consent process; therefore, patient blinding will not be implemented. However, radiographic evaluators, histomorphometric assessors, and data analysts will remain blinded to group allocation throughout outcome assessment and statistical analysis. Group coding will be performed by an independent researcher who is not involved in treatment delivery or outcome evaluation. Allocation information will be disclosed only after completion of the final statistical analysis

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad Faculty of Dentistry

Street address

Faculty of Dentistry, Ferdowsi University of Mashhad, West Gate, Vakilabad Boulevard

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2026-05-02, 1405/02/12

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1405.020

Health conditions studied

1

Description of health condition studied

socket closure

ICD-10 code

K08.1

ICD-10 code description

Complete loss of teeth

Primary outcomes

1

Description
percentage of epithelial coverage of socket orifice
Timepoint
Day 0 (immediately after the intervention), 1 week after the intervention, 2 weeks after the intervention, and 4 weeks after the intervention
Method of measurement
In this study, ImageJ software will be used to assess percentage changes in epithelialized surface area at different follow-up intervals. After importing the images into the software, the Freehand Selection tool will be used to delineate the stained areas, which will be considered non-epithelialized regions. In contrast, the unstained areas after methylene blue application will be regarded as epithelialized regions. The epithelialized and non-epithelialized areas will then be quantified as a percentage of the total surface area in each image.

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention Group 1": After tooth extraction and socket preparation, immediate implant placement will be performed in the fresh socket during the same treatment session. The socket entrance will be covered using an absorbable collagen matrix (Collagen Matrix). This material is a xenogenic biomaterial derived from type I collagen and, after hydration, will be placed over the socket entrance and fixed with sutures. The collagen matrix used belongs to the Coltene company, Switzerland. The dimensions of the collagen matrix are 14*7*7 mm. This material is a sponge-like scaffold made of animal-derived gelatin with a porous structure.
Category
Treatment - Surgery

2

Description
"Intervention Group 2": After tooth extraction and socket preparation, immediate implant placement will be performed in the fresh socket during the same treatment session. The socket entrance will be covered using an Acellular Dermal Matrix (ADM). This material is prepared from human dermal tissue after complete removal of cellular components and acts as a biological scaffold for soft tissue regeneration. ADM will be placed over the socket entrance after hydration and will be fixed with sutures. This material is manufactured by Iranian Tissue Products Company. The thickness of the material used is 0.2 to 0.6 mm, and its dimensions are 10*15 mm. Its chemical composition is cadaveric human skin dermis from which the cells have been removed, and the remaining extracellular matrix is preserved.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Mashhad University of Medical Sciences
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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Farid Shiezadeh
Position
associate Professor
Latest degree
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Person responsible for updating data

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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
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
Data related to age, gender, baseline and follow-up photographic images, initial non-epithelialized surface area, involved tooth locations and percentage of epithelialized surface at the recorded time points will be available for sharing. All data will be anonymized and stripped of any personal identifiers to ensure patient confidentiality.
When the data will become available and for how long
The data access period will begin 6 months after the publication of the study results.
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
If other researchers require access to the data,

methodology, or analyses used in this study for the purpose of writing articles or theses, the data can be shared while maintaining confidentiality and excluding any patient-identifying information.

From where data/document is obtainable

The data can be shared upon request via email at msaeid19971376@gmail.com

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

The data will be provided within a short period after the request is received.

Comments