Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Clinical Evaluation of the Impact of Socket Preservation Using Collagen-Based Clot Retention Compared to Conventional Methods on Wound Healing Following Tooth Extraction in Patients Requiring Tooth Extraction

Protocol summary

Study aim
Comparing clinical outcomes and soft tissue healing in atraumatic tooth extraction with and without the use of Collacone collagen wound dressing

Design
Parallel-group, single-blind clinical trial. Participants are non-randomly assigned to two intervention groups (use of clot-preserving collagen) and control (no use of clot-preserving collagen).

Settings and conduct
The study will be conducted at the Orthodontics and Oral Surgery departments of Shahid Beheshti University of Medical Sciences, Dental School. It will involve atraumatic tooth extractions, with soft tissue measurements and evaluation of healing outcomes at 2 and 4 weeks post-extraction.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients requiring bilateral premolar extractions due to orthodontic treatment; informed consent given. Exclusion criteria: Systemic diseases (e.g., diabetes); history of infection, abscess, or uncontrolled oral conditions; use of immunosuppressive drugs or antibiotics; smoking; non-consent

Intervention groups
Intervention group: Patients in the intervention group will receive collagen clot-preserving material in the socket of the extracted tooth. Control group: Patients in the control group will not receive any material in their socket.

Main outcome variables
Soft tissue healing (mesiodistal and buccolingual ridge dimensions); pain level; bleeding level (none/slight/major); swelling level (none/localized/severe); post-operative comfort.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241204063947N1**
Registration date: **2025-02-04, 1403/11/16**
Registration timing: **retrospective**

Last update: **2025-02-04, 1403/11/16**
Update count: **0**

Registration date
2025-02-04, 1403/11/16

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-07-23, 1396/05/01

Expected recruitment end date
2018-04-22, 1397/02/02

Actual recruitment start date
2017-03-02, 1395/12/12

Actual recruitment end date
2018-01-02, 1396/10/12

Trial completion date
2018-01-02, 1396/10/12

Scientific title
Clinical Evaluation of the Impact of Socket Preservation

Using Collagen-Based Clot Retention Compared to Conventional Methods on Wound Healing Following Tooth Extraction in Patients Requiring Tooth Extraction

Public title
Socket Preservation with Collagen and Its Impact on Post-Extraction Healing
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy people without systemic diseases Adults aged 18 to 65 years Patients undergoing simple tooth extraction Patients who are candidates for extraction of bilateral premolars for orthodontic treatment Patients who provided full and informed consent to participate in the study
Exclusion criteria:
People who are prohibited from performing dental procedures History of allergy to collagen or related substances Presence of active oral infections Using immunosuppressive drugs or antibiotics Smoking
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **20**
Actual sample size reached: **16**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
The treatment boxes are sealed with 10-digit codes, and each code contains either the original treatment (clot-preserving collagen) or the alternative treatment (no clot-preserving collagen). The researcher will ensure that patients are completely unaware of their treatment by closely monitoring the treatment process.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Tehran Province, Tajrish، Velenjak، 7th Floor, Bldg No.2 SBUMS, Arabi Ave, Iran
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Province
Tehran
Postal code
1985717443
Approval date
2017-05-20, 1396/02/30
Ethics committee reference number
IR.SBMU.RIDS.REC.1396.458

Health conditions studied

1

Description of health condition studied
Atraumatic tooth extraction, soft tissue healing
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Soft tissue healing
Timepoint
At baseline (immediately post-extraction), and at 14 and 28 days after the procedure.
Method of measurement
Wound closure and presence of any signs of infection or inflammation.

Secondary outcomes

1

Description
Pain level
Timepoint
At baseline (immediately post-extraction), and at 14 and 28 days after the procedure.
Method of measurement
Visual Analogue Scale

2

Description
Infection rate
Timepoint
At baseline (immediately post-extraction), and at 14 and 28 days after the procedure.
Method of measurement
Clinical evaluation for signs of infection such as redness, swelling, pus, or increased pain at the extraction site.

3

Description
Patient satisfaction
Timepoint
At baseline (immediately post-extraction), and at 14 and 28 days after the procedure.
Method of measurement
5-point Likert scale, where 1 is "very dissatisfied" and 5 is "very satisfied."

4

Description
Swelling
Timepoint
At baseline (immediately post-extraction), and at 14 and 28 days after the procedure.
Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group: The tooth extraction was performed conservatively and bilaterally. On one side, the dental socket was managed using natural collagen (Collacone, Botiss Biomaterials, Germany). For this purpose, after administering local anesthesia with (Persocaine-E; Daroupakhsh, Tehran, Iran), the periodontal ligaments were separated using a periosteal elevator, and the tooth was extracted conservatively using universal forceps (Aesculap Co, USA) with vertical and rotational pressure. In the intervention group, a piece of Collacone with dimensions (e.g., 10 × 10 × 5 mm, if specified) was placed inside the dental socket. The socket opening was then closed using 4-0 Vicryl absorbable sutures (Ethicon, Johnson & Johnson, NJ, USA) in a horizontal mattress technique.
Category
Treatment - Surgery

2

Description
Control group: The same surgical and suturing procedures were followed, but no collagen material was applied.Postoperative care instructions, including oral hygiene guidelines, dietary recommendations, and pain management with Gelofen (Ibuprofen 400 mg, Daana Pharma, Iran), were provided. Sutures were removed one week postoperatively.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental School, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zeinab Bakhtiari
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
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Position
Researcher
Latest degree
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Person responsible for updating data

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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
We do not share the data. Individual participant data will not be published due to ethical considerations and patient privacy concerns.
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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
.
When the data will become available and for how long
.
To whom data/document is available
.
Under which criteria data/document could be used
.
From where data/document is obtainable
.
What processes are involved for a request to access data/document
.
Comments