

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Name

zeinab Bakhtiari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

zeinabbakhtiari@sbmu.ac.ir

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		Ethics committee of Shahid Beheshti University of Medical Sciences	
Public title	Socket Preservation with Collagen and Its Impact on Post-Extraction Healing	Street address	Tehran Province, Tajrish, Velenjak, 7th Floor, Bldg No.2 SBUMS, Arabi Ave, Iran
Purpose	Treatment	City	Tehran
Inclusion/Exclusion criteria		Province	Tehran
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	Postal code	1985717443
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	Approval date	2017-05-20, 1396/02/30
Age	From 18 years old to 65 years old	Ethics committee reference number	IR.SBMU.RIDS.REC.1396.458
Gender	Both	Health conditions studied	
Phase	N/A	1	
Groups that have been masked	Participant	Description of health condition studied	
Sample size	Target sample size: 20 Actual sample size reached: 16	Atraumatic tooth extraction, soft tissue healing	
Randomization (investigator's opinion)	Not randomized	ICD-10 code	
Randomization description		ICD-10 code description	
Blinding (investigator's opinion)	Single blinded	Primary outcomes	
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.	1	
Placebo	Used	Description	
Assignment	Parallel	Soft tissue healing	
Other design features		Timepoint	
Secondary Ids		At baseline (immediately post-extraction), and at 14 and 28 days after the procedure.	
empty		Method of measurement	
Ethics committees		Wound closure and presence of any signs of infection or inflammation.	
1		Secondary outcomes	
Ethics committee		1	
Name of ethics committee		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.	

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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."

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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

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zeinab Bakhtiari

Street address

Tehran Province, Tajrish, Velenjak, 7th Floor, Bldg No.2 SBUMS, Arabi Ave, Iran

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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

Full name of responsible person

Zeinab Bakhtiari

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Researcher

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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**