

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of Gelfoam and Bonehem in dental socket bleeding control in patients on low-dose Aspirin

Protocol summary

Study aim

Comparison of Gelfoam and Bonehem in dental socket bleeding control in patients on low-dose Aspirin

Design

A clinical trial with a control group, with parallel groups, double-blinded, randomized, phase 2 on 30 patients. A table of random numbers was used for randomization.

Settings and conduct

After approval by the Research Council of Shahid Beheshti Dental School, randomization will be done among the patients eligible to participate in the study, and they will be randomly divided into 3 groups. The study will be double-blinded in all three groups (patients and researchers are blinded). After tooth extraction, a method of hemostasis will be used based on each group, and post-treatment recommendations will be provided. the number of sterile gauze used after the treatment will show the results.

Participants/Inclusion and exclusion criteria

Inclusion criteria: healthy patients between the ages of 30 and 75 with ASA I-II treated with one 80 mg aspirin tablet daily who are candidates for non-surgical extraction of mandibular first or second molar teeth. Exclusion criteria: patients using other doses or different amounts of aspirin, using other anticoagulant drugs along with aspirin, candidate for socket preservation; with contraindications to use Bonehem (areas with infection) and Gelfoam (known allergy to porcine collagen); with wound healing disorders, with bone diseases, diagnosed with diabetes mellitus; diagnosed with autoimmune diseases; candidates for surgical tooth extraction, candidates for immediate implant placement.

Intervention groups

1: Patients in whom Gelfoam is used to control bleeding from the tooth socket. 2: Patients in whom Bonehem is used to control bleeding from the tooth socket. 3: patients in whom a figure-of-eight suture is used to control bleeding from the tooth socket.

Main outcome variables

Dental socket bleeding post-tooth extraction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221220056881N1**

Registration date: **2022-12-30, 1401/10/09**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-30, 1401/10/09**

Update count: **0**

Registration date

2022-12-30, 1401/10/09

Registrant information

Name

Mohammad Hassan Mirtaleb

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2270 1377

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mirtalebmohamad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Comparison of Gelfoam and Bonehem in dental socket bleeding control in patients on low-dose Aspirin
Public title	Effect of Bonehem in Hemostasis
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Healthy patients (ASA I/II) Under treatment with a single 80mg dose of Aspirin tablet daily Candidate for non-surgical removal of mandibular first and second molar teeth
Exclusion criteria:	
Age	From 30 years old to 75 years old
Gender	Both
Phase	3
Groups that have been masked	• Participant • Care provider
Sample size	Target sample size: 30
Randomization (investigator's opinion)	Randomized
Randomization description	People are randomly allocated to one of the three study groups using a random number and receive the intervention based on the group. First, a random number is allocated to each group; Coefficients of the number 3 are allocated to the first group, coefficients of 3 plus 1 are allocated to the second group, and coefficients of 3 plus 2 are allocated to the third group. For the distribution of the patients to each group, first, the direction of reading the numbers from the table is determined and then the researcher touches one of the numbers randomly and moves in one of the predetermined directions and records the numbers, and assigns the patient to the specified group.
Blinding (investigator's opinion)	Double blinded
Blinding description	The study will be double-blinded. Patients are blinded to the type of intervention, and the researcher who has to enter the data into the checklist will be blinded to the type of intervention.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Shahid Beheshti University of Medical Sciences Ethics Committee
Street address	Shahid Beheshti University of Medical Sciences, Daneshjoo Blvd., Evin, Chamran Highway, Tehran
City	Tehran
Province	Tehran
Postal code	1983963113
Approval date	2022-11-14, 1401/08/23
Ethics committee reference number	IR.SBMU.DRC.REC.1401.070

Health conditions studied	
1	
Description of health condition studied	Bleeding after extraction of mandibular first and second molar teeth
ICD-10 code	T81.0
ICD-10 code description	Haemorrhage and haematoma complicating a procedure, not elsewhere classified
Primary outcomes	
1	
Description	socket haemorrhage
Timepoint	24 hours after tooth extraction
Method of measurement	number of sterile gauze required to stop bleeding after tooth extraction

Secondary outcomes	empty
Intervention groups	
1	
Description	Intervention group: a single Gelfoam (Surgifoam, Ethicon) is used on the dental socket after extraction without suturing the socket. A 10x10 sterile gauze is then placed on the socket and the patient is guided to slowly bite on the gauze.
Category	

Treatment - Drugs

2

Description

Intervention group: a single Bonhem (from Chitotech company, based on hydroxyapatite and bioglass) is used on the dental socket after extraction without suturing the socket. A 10x10 sterile gauze is then placed on the socket and the patient is guided to slowly bite on the gauze.

Category

Treatment - Drugs

3

Description

Control group: A 3-0 silk (Supasil) figure-of-eight suture is used to suture the dental socket after extraction. A 10x10 sterile gauze is then placed on the socket and the patient is guided to slowly bite on the gauze.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Dental School

Full name of responsible person

Doctor Fateme Latifi

Street address

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info@sbmu.ac.ir

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https://dentistry.sbmu.ac.ir

2

Recruitment center

Name of recruitment center

Behfar Dental Clinic

Full name of responsible person

Shiva Reyvandi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

ChitoTech

Full name of responsible person

Ms. Mohammadi

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Units 9 and 11, Khaghani Building, No 83, Somayyeh
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1571838318

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Email

info@chitotech.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

ChitoTech

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Hassan Mirtaleb

Position

Dental Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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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

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

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

Related medical information, clinical information, results of the study

When the data will become available and for how long

Approximately 6 months after publication

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

More detailed information about the study can be provided to competent researchers interested in the subject of the study

From where data/document is obtainable

Author (Mohammad Hassan Mirtaleb) via email:
mirtalebmoahamad@gmail.com

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

Competent and enthusiastic researchers can receive data documentation after the publication of the work from the corresponding author by providing their academic information and identification.

Comments