

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

Dental socket bleeding post-tooth extraction

##### 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

#### 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)

##### Phone

+98 21 2270 1377

##### Email address

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

Shahid Beheshti University of Medical Sciences,  
Daneshjoo Blvd., Evin, Chamran Highway, Tehran

##### City

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##### Province

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##### Postal code

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##### Phone

+98 21 2217 5350

##### Email

info@sbmu.ac.ir

##### Web page address

https://dentistry.sbmu.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Behfar Dental Clinic

##### Full name of responsible person

Shiva Reyvandi

##### Street address

Damavand Street, Tehran

##### City

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##### Province

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##### Postal code

1644914989

##### Phone

+98 21 7781 3948

##### Email

info@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

ChitoTech

##### Full name of responsible person

Ms. Mohammadi

##### Street address

Units 9 and 11, Khaghani Building, No 83, Somayyeh  
street, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1571838318

##### Phone

+98 21 8832 1518

##### 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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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Position**  
Assistant Professor  
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Specialist  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Mohammad Hassan Mirtaleb  
**Position**  
Dental Student  
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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:  
mirtalebmohamad@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