Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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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

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Tehran

Province
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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
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Ms. Mohammadi
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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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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 publishment

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