Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the Effect of Hydroalcoholic Extract of Mespilus germanica L. Fruit on the Control of Alveolar Socket Bleeding after Mandibular Molars Extraction

Protocol summary

Study aim

Determining the average control time of alveolar Socket bleeding after using gauze impregnated with 20% and 40% extract of Mespilus germanica L. and gauze impregnated with normal saline.

Design

Clinical trial with first intervention group (20% extract), second intervention group (40% extract), and control group (normal saline) with parallel groups, Three blind strains, Randomized, Phase 3 trial on 90 patients, Random allocation2 software was used for randomization.

Settings and conduct

In the department of surgery of Mazandaran university of medical sciences, sterilized gauzes in wet thermal autoclave with 4 cc extracts of 40 % and 20 % and normal saline are impregnated and then dried the gauzes in oven. the tooth is extracted by simple extraction method. The gauze is put into the patient's mouth with mild contact and soaked with normal saline. Every 5 minutes the gauze is removed from the patient's mouth and the bleeding or discontinuation is recorded. Due to the color matching of the solutions, the evaluator, patient, and statistical consultant participate in blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mandibular Molars Extraction and Age ≥ 18 years, Insensitivity to the extract, Patients with ASA I and II, No smoking and hookah, Amenorrhea during surgery, Not using contraceptives, Not having a clotting disorder, Absence of uncontrolled infection at the surgical site Exclusion criteria: The presence of a large periapical lesion, the complications during surgery such as flap rupture, Patients with moderate and severe periodontal disease

Intervention groups

Gauze impregnated with 20% extract of Mespilus germanica L. (A - treatment group) Gauze impregnated with 40% extract of Mespilus germanica L. (B - treatment group) Gauze impregnated with normal saline (C - control group)

Main outcome variables

Bleeding rate (clot formation) Bleeding control time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240928063195N1**
Registration date: **2024-12-09, 1403/09/19**
Registration timing: **prospective**

Last update: **2024-12-09, 1403/09/19**
Update count: **0**

Registration date

2024-12-09, 1403/09/19

Registrant information

Name

Mahsa Zare

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

2025-04-03, 1404/01/14

Expected recruitment end date

2025-06-08, 1404/03/18

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effect of Hydroalcoholic Extract of Mespilus germanica L. Fruit on the Control of Alveolar Socket Bleeding after Mandibular Molars Extraction

Public title
Evaluation of the Effect of Mespilus germanica L. Fruit Extract on the Control of Alveolar Socket Bleeding after Mandibular Molars Extraction
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Mandibular Molars Extraction Age ≥ 18 years Insensitivity to Mespilus germanica L. Fruit extract Not using complementary medical methods (herbal drugs, etc.) in the last month Not having a clotting disorder Absence of acute or uncontrolled infection at the surgical site Patients with ASA I and II and absence of any uncontrolled medical problem Not using contraceptives in the last month Not using any medication that interferes with bone repair and blood coagulation No smoking and hookah Amenorrhea during surgery
Exclusion criteria:
Patients with a large periapical lesion Patients with complications during surgery such as flap rupture Patients with moderate and severe periodontal disease
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
People who met the entry criteria were placed in two treatment groups and one control group. sterile gauzes soaked with extract of 20 % and 40 % Mespilus germanica L. were used for treatment group and sterile gauzes soaked with normal saline were used for control group. random block method will be used to allocate samples to three groups. For this purpose, patients will receive the number 1 to 90 according to the selection order. The randomization unit will be individually and by number with blocks of three people. The selection of the group type for each person will be done through random allocation2 statistical software. In order to construct a random sequence, codes A, B and C will be generated from the software, where code A means applying the the first intervention group (20% extract) and code B means applying the second intervention group (40% extract) and Code C means applying the control group to each person. Finally, the codes will be placed in the sealed envelope and the number of each patient will be written on the envelope. As each patient enters, the doctor will open the envelope and apply the desired treatment.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Due to the homogenization of the color of the normal saline solution and the extracts with each other, the evaluator, the patient and the statistical consultant are involved in blinding.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
No.9, 9th Keshavarz Alley, Keshavarz Blvd, Sari Town
City
Sari
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Mazandaran
Postal code
4813797981
Approval date
2024-07-09, 1403/04/19
Ethics committee reference number
IR.MAZUMS.REC.1403.189

Health conditions studied

1

Description of health condition studied
Control of Alveolar Socket Bleeding after Mandibular Molars Extraction
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Percentage of people who have faster bleeding control with gauze impregnated with Mespilus germanica L. extract

Timepoint
Measuring the clot formation time every 5 minutes after starting to place the gauze on the socket of the extracted tooth

Method of measurement
Every 5 minutes, the formation or non-formation of a clot in the socket of the extracted tooth is confirmed by the maxillofacial surgeon.

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: gauze impregnated with a 20% extract of Mespilus germanica L. : The tooth is extracted by simple extraction without flap removal, bone removal, and odontotomy. After cleaning the socket, sterile gauze soaked in 20% Mespilus germanica L. extract is given to the maxillofacial surgeon by the student and used for the first treatment group. After the gauze is placed in the patient's mouth, the dried gauze is moistened with normal saline and the patient is asked to press the gauze so that the opposing tooth or ridge touches the gauze and the light and acceptable contact is confirmed by the maxillofacial surgeon. At this stage, the patient is instructed to avoid any activity that may increase bleeding, such as opening the mouth, emptying saliva, or talking. In each group, gauze is removed from the patient's mouth every 5 minutes and bleeding or cessation is recorded. To prevent the formed clot from dislodging, gas removal is performed gently by an oral and maxillofacial surgeon.

Category
Prevention

2

Description
The second intervention group: gauze impregnated with a 40% extract of Mespilus germanica L. : The tooth is extracted by simple extraction without flap removal, bone removal, and odontotomy. After cleaning the socket, sterile gauze soaked in 40% Mespilus germanica L. extract is given to the maxillofacial surgeon by the student and used for the first treatment group. After the gauze is placed in the patient's mouth, the dried gauze is moistened with normal saline and the patient is asked to press the gauze so that the opposing tooth or ridge touches the gauze and the light and acceptable contact is confirmed by the maxillofacial surgeon. At this stage, the patient is instructed to avoid any activity that may increase bleeding, such as opening the mouth, emptying saliva, or talking. In each group, gauze is removed from the patient's mouth every 5 minutes and bleeding or cessation is recorded. To prevent the formed clot from dislodging, gas removal is performed gently by an oral and maxillofacial surgeon.

Category
Prevention

3

Description
Control group: gauze impregnated with normal saline. : The tooth is extracted by simple extraction without flap removal, bone removal, and odontotomy. After cleaning the socket, sterile gauze soaked in normal saline is given to the maxillofacial surgeon by the student and used for control group. After the gauze is placed in the patient's mouth, the dried gauze is moistened with normal saline and the patient is asked to press the gauze so that the opposing tooth or ridge touches the gauze and the light and acceptable contact is confirmed by the maxillofacial surgeon. At this stage, the patient is instructed to avoid any activity that may increase bleeding, such as opening the mouth, emptying saliva, or talking. In each group, gauze is removed from the patient's mouth every 5 minutes and bleeding or cessation is recorded. To prevent the formed clot from dislodging, gas removal is performed gently by an oral and maxillofacial surgeon.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Surgery, Faculty of Dentistry, Mazandaran University of Medical Sciences

Full name of responsible person
Dr Amirhossein Moaddabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person

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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Mahsa Zare

Position

Dental Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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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)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available