Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of Eugenol by gelfoam carrier in preventing dry socket syndrome following surgical extraction of the impacted third molar of the mandible

Protocol summary

Study aim
The effectiveness of the use of Eugenol in preventing the occurrence of dry socket syndrome after mandibular third molar surgery

Design
This study is a randomized clinical trial, single-blind, phase III clinical trial with a split-mouth design, conducted on 36 patients, using restricted block randomization.

Settings and conduct
This study is a randomized controlled trial (RCT). The research will be conducted on patients referred to the Department of Oral and Maxillofacial Surgery at the Islamic Azad University, Tehran Dental School, during the academic year 2024–2025. Eugenol used in the surgery will be applied with a Gelfoam carrier. In the intervention group, the area will be irrigated and the socket filled with Gelfoam impregnated with eugenol, followed by suturing. Then, in both groups, a sterile gauze will be placed in the area for 30 minutes. The study is single-blinded, and only one evaluator will be involved.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18 and 35 years, lower mandibular third molar teeth, bilaterally Exclusion criteria: Uncontrolled systemic conditions

Intervention groups
All patients undergo surgical extraction of the lower third molar by the same surgeon. After tooth removal, the socket is irrigated, and in the intervention side, the socket is filled with Hemospong gel containing one drop of Eugenol (produced by Golchay Company). In the control side, the socket is only irrigated, and then—similar to the intervention side—the area is sutured using 3/0 Vicryl suture with a 26 mm needle. After irrigation, suturing is performed in the same way for both groups. A sterile gauze is then placed in the surgical site for 30 minutes in both groups. All patients are prescribed amoxicillin 250 mg capsules every 8 hours and ibuprofen 500 mg tablets every 6 hours.

Main outcome variables
Occurrence of dry socket

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250204064639N1**
Registration date: **2025-06-04, 1404/03/14**
Registration timing: **registered_while_recruiting**

Last update: **2025-06-04, 1404/03/14**
Update count: **0**

Registration date
2025-06-04, 1404/03/14

Registrant information

Name
Niyayesh sadat Mirjafari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 7736 2969

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h.mesgari@iautmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-16, 1404/01/27

Expected recruitment end date
2025-08-11, 1404/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Eugenol by gelfoam carrier in preventing dry socket syndrome following surgical extraction of the impacted third molar of the mandible

Public title

Investigating the effect of Eugenol by gelfoam carrier in preventing dry socket syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 35 years The impacted third molars of the mandible bilaterally placed In class I, II and III, level A, B and C based on the classification of Paul and Gary Gouri Need to remove the tooth surgically

Exclusion criteria:

Uncontrolled systemic conditions

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **72**

More than 1 sample in each individual

Number of samples in each individual: **2**

The research is split mouth; on one side of the patient's jaw, an intervention Eugenol is used, along with a foam gel carrier. On the other side, no drug is used, and it is left without intervention.

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method in this study is block randomization with a fixed block size of 2. This study is designed as a split-mouth trial, meaning that in each participant, one side of the mouth (right or left) will be randomly assigned to the intervention group (application of Eugenol with Gel Foam), and the opposite side will be assigned to the control group (no pharmaceutical intervention). For the random allocation of the intervention side, Random Allocation Software version 1.0 (RAS, ©M. Saghaei, 2004, Isfahan University of Medical Sciences) will be used. The random sequence will be prepared before the start of the study, placed in opaque, sealed, and sequentially numbered envelopes, and used in order of participant enrollment to ensure allocation concealment.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluator is unaware of the type of intervention performed, and the study is conducted as a single-blind trial.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Dentistry Faculty - Islamic Azad University of Medical Sciences

Street address

No. 9, Pasdaran St., Nistan 9th

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2024-10-14, 1403/07/23

Ethics committee reference number

IR.IAU.DENTAL.REC.1403.136

Health conditions studied

1

Description of health condition studied

Dry socket

ICD-10 code

M27

ICD-10 code description

Other diseases of jaws

Primary outcomes

1

Description

dry socket syndrome Incidence

Timepoint

1,3 And 7 days after the intervention on both the intervention and control sides.

Method of measurement

Evaluation through clinical observation by an oral and maxillofacial surgeon

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All patients underwent mandibular wisdom tooth extraction by the same surgeon. The type of incision in all procedures was the same, a buccal flap with distobuccal releasing, along with a sulcular incision to the mesial of the seventh tooth. After anesthesia, incision, and flap removal, a portion of the bone covering the tooth will be removed with a surgical bur. After sectioning the tooth and removing it, the area on the intervention side is rinsed and the socket will be filled with one piece of Hemospan gel foam soaked with one drop of eugenol (manufactured by Golchai Company). Then, it is sutured using 3/0 chromic thread and a 26mm needle, and then a sterile gauze is placed in the area for half an hour. For better control and elimination of the effect of the infectious agent, all patients will be prescribed Amoxicillin 250 mg capsules every 8 hours and Gelofen 500 mg tablets every 6 hours to control possible pain. The patient is asked to do the following in the first 24 to 48 hours: 1- Consume cold foods and liquids such as: cold milk, cold soup, cold fruit juice, ice cream, etc. 2- Do not consume hot or chewy foods. 3- Avoid brushing the area where the tooth was extracted. 4- Avoid smoking and do not spit (spit) your saliva. 5- Avoid irritating the area where the tooth was extracted with your hands or tongue. 6- Avoid heavy exercise and physical work and prioritize rest. One day after surgery, normal saline solution should be used as a mouthwash at least five times daily for one week. One day, three days, and seven days after the extraction of the impacted third molar, the patient is contacted for clinical assessment of dry socket or absence of dry socket.

Category

Prevention

2

Description

Control Group: All patients undergo surgical extraction of the lower third molar by the same surgeon. The type of incision is the same in all procedures: a buccal flap with a distobuccal releasing incision, along with a sulcular incision extending to the mesial of the second molar. After administering anesthesia, making the incision, and reflecting the flap, a surgical bur is used to remove part of the bone covering the tooth. After sectioning and removing the tooth, the control site is irrigated and sutured using 3/0 chromic gut suture with a 26 mm needle. A sterile gauze is then placed at the site for 30 minutes. To better control and eliminate the effect of infection, all patients are prescribed amoxicillin 250 mg capsules every 8 hours and ibuprofen 500 mg tablets every 6 hours for pain control. Patients are instructed to follow postoperative care guidelines during the first 24 to 48 hours.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Islamic Azad University of Medical Sciences - Faculty of Dentistry, Tehran branch

Full name of responsible person
Hassan Mesgari

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No. 9, Pasdaran St., Nistan 9th

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

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
Islamic Azad University

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
Islamic Azad University

Full name of responsible person
Hassan Mesgari

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Niyayesh Sadat Mirjafari

Position
Student of general dentistry

Latest degree
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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