Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of dexamethasone 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 Dexamethasone in Preventing Dry Socket Syndrome Following Mandibular Third Molar Surgery

Design

A parallel, split-mouth, single-blind, randomized, phase 3 trial on 36 patients. The randomization will be performed using a sealed envelope containing a predetermined random sequence.

Settings and conduct

This study is a randomized controlled trial. Data are collected from a clinical trial involving patients referred to the Department of Maxillofacial Surgery at the Islamic Azad University Dental School during 2024–2025. In the intervention group, after irrigation of the surgical site, the cavity is filled with dexamethasone-impregnated foam gel and sutured. A sterile gauze pad is placed over the site for 30 minutes in both groups. Blinding is single-sided, with only the evaluator being blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 35 years, presence of bilateral impacted mandibular third molars Exclusion criteria: presence of uncontrolled systemic diseases

Intervention groups

All patients will undergo mandibular third molar extraction performed by the same surgeon. A buccal flap with a distobuccal releasing incision and a sulcular incision extending to the mesial aspect of the second molar will be made. Following local anesthesia, the incision is performed, the flap is reflected, and a portion of the bone covering the tooth is removed using a surgical bur. After extracting the tooth, the surgical site is irrigated, and the socket is filled with a dexamethasone-containing foam gel. The flap is then repositioned and sutured using 3-0 Vicryl sutures with a 26 mm needle. A sterile gauze pad is placed over the surgical site for 30 minutes in both groups. All patients are prescribed amoxicillin 250 mg capsules every 8 hours and Gelofen 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: **IRCT20250204064640N1**
Registration date: **2025-04-26, 1404/02/06**
Registration timing: **registered_while_recruiting**

Last update: **2025-04-26, 1404/02/06**
Update count: **0**

Registration date

2025-04-26, 1404/02/06

Registrant information

Name

Fateme TorkYelmaz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2264 8291

Email address

fateme.torkyelmaz@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-09, 1404/01/20

Expected recruitment end date

2025-05-10, 1404/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of dexamethasone 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 dexamethasone 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 (dexamethasone) 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

In this study, we used the restricted randomization method randomization (block randomization type) We will use randomization. Blocking is usually used in order to Creating a balance in the number of samples assigned to each of the groups be used for study. This feature helps researchers to Cases that require intermediate analyzes during the sampling process be the number of samples assigned to each of the case groups The study is equal. The size of all the blocks is equal and we are in this Single-group trial of 4 blocks (including 4 participants in We will have an intervention group and a control). The randomization tool is also from sequence generation software Random (random software allocation) is used that this Random sequence generation software is capable of simple randomization They are used to generate random sequences using the block method. To hide We use Concealment Allocation We use the method used to execute the sequence Randomization is applied to the participants in the study, in a way Before assigning the individual, the assigned group is not clear. With from sealed opaque envelopes with random sequence (envelopes opaque, sealed, numbered Sequentially (which in In this method, each random sequence is created on a card It is registered and the cards are placed in the envelopes in order become In order to preserve the random sequence on the outer surface of the envelope Numbering is done in the same order. Finally, the envelope door The letters are glued and placed in a box in order. At The time of starting the registration of participants, based on the order of entry of the company Eligible candidates to study, one of the letter envelopes in open order and the assigned group of that participant is revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluator is unaware of the type of intervention, and the study is conducted in a single-blind manner.

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.1403.137

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
The occurrence or absence of dry socket syndrome
Timepoint
1, 3 and 7 days after surgery 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 undergo mandibular wisdom tooth extraction by the same surgeon. The type of incision in all procedures is the same: a buccal flap with distobuccal release, 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 cavity is filled with dexamethasone-impregnated gel foam. 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 mandibular wisdom tooth extraction by the same surgeon. The type of incision in all procedures is 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. 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

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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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 scientific inquiries

Contact

Name of organization / entity
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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
Islamic Azad University

Full name of responsible person
Fateme TorkYelmaz

Position
Student of general dentistry

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