Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the Effect of Dexamethasone-Impregnated Gelfoam Placement in the Socket on Postoperative Pain Following Impacted Mandibular Third Molar Surgery

Protocol summary

Study aim

To determine the effect of placing dexamethasone-impregnated Gelfoam in the socket on reducing postoperative pain following impacted mandibular third molar surgery, and to compare pain intensity between the intervention and control sides.

Design

A randomized double-blind clinical trial with a Split-mouth design on 35 patients (70 samples), each patient serving as their own control. Randomization using a table of random numbers determines the surgical side and intervention type. The patient and outcome assessor are blinded to the intervention, while the surgeon is aware.

Settings and conduct

This study is conducted at the Department of Oral and Maxillofacial Surgery, Dental School, and Shafieh Specialized Clinic of Zanjan University of Medical Sciences. After screening and obtaining informed consent, patients are randomized and standard surgery is performed by a single surgeon. In each session, the respective Gelfoam is placed in the socket and the wound is closed. The contra

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18-30 years; bilateral symmetrical impacted third molars; complete systemic health (ASA I); willingness to cooperate. Exclusion criteria: uncontrolled systemic disease; smoking/alcohol; pregnancy/breastfeeding; hypersensitivity to dexamethasone, Gelfoam or anesthetics; active infection at surgical site; NSAIDs/corticosteroids within 7 days; dry socket after surgery.

Intervention groups

Intervention group: placement of Gelfoam impregnated with 8 mg dexamethasone (dissolved in 2 ml normal saline) in the tooth socket after extraction of impacted third molar. Control group: placement of Gelfoam impregnated with 2 ml normal saline in the socket. Both groups receive standard antibiotic and oral analgesic.

Main outcome variables

Pain intensity by VAS on days 1,3,7 post-surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260629070000N1**
Registration date: **2026-07-11, 1405/04/20**
Registration timing: **prospective**

Last update: **2026-07-11, 1405/04/20**
Update count: **0**

Registration date

2026-07-11, 1405/04/20

Registrant information

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-01, 1405/05/10

Expected recruitment end date

2026-12-21, 1405/09/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effect of Dexamethasone-Impregnated Gelfoam Placement in the Socket on Postoperative Pain Following Impacted Mandibular Third Molar Surgery

Public title
Effect of Dexamethasone in Wisdom Tooth Surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 35 years. Presence of bilaterally impacted mandibular third molars with similar impaction position (according to the Pell and Gregory classification) to ensure matching. American Society of Anesthesiologists (ASA) Physical Status I (healthy patients with no systemic disease). Willingness to cooperate and complete the follow-up visits in both surgical sessions.
Exclusion criteria:
History of cigarette smoking or alcohol consumption (due to their negative effects on wound healing and increased risk of dry socket). (based on the patient's dental record and medical history) Pregnancy or breastfeeding. History of hypersensitivity to dexamethasone, Gelfoam, or local anesthetic agents. (based on the patient's dental record and medical history) Presence of active infection (e.g., pericoronitis) or any lesion at the surgical site. (based on clinical examination before surgery) Use of nonsteroidal anti-inflammatory drugs (NSAIDs) or corticosteroids within 7 days before surgery. Development of dry socket after surgery (the participant will be withdrawn from the study and receive standard treatment immediately).
Age
From **18 years** old to **30 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **35**
More than 1 sample in each individual
Number of samples in each individual: **2**
This study employs a split-mouth design. Each patient has two symmetrical impacted mandibular third molars that both require surgery. One side (right or left) is designated as the intervention group (receiving Gelfoam impregnated with dexamethasone) and the other side as the control group (receiving Gelfoam impregnated with normal saline). Therefore, two samples (two tooth sockets) are obtained from each participant.

Randomization (investigator's opinion)
Randomized
Randomization description
In this randomized clinical trial with a Split-Mouth design, a randomization method using a table of random numbers is employed to eliminate confounding effects related to the "surgical side" (right or left) and the "surgical sequence" (first or second operation). After eligible patients are selected, a randomization list is prepared by an individual independent of the study (e.g., a statistician). This list randomly determines which side of the jaw (right or left) will undergo surgery in the first session and which side will receive the main intervention (Gelfoam impregnated with dexamethasone) and which side will receive the control intervention (Gelfoam impregnated with normal saline). In other words, each patient acts as their own control, and both the order of surgery and the type of intervention for each side are determined randomly. An example of the random number table method is as follows: Suppose there are two study groups (A and B) and six participants who need to be randomly allocated. One row of a random number table is selected arbitrarily, where each number ranges from 0 to 9. Numbers 0–4 are assigned to Group A, and numbers 5–9 are assigned to Group B. Assume the selected row contains the following sequence: 0, 5, 2, 7, 8, 4. Accordingly, the number 0 is allocated to Group A, 5 to Group B, 2 to Group A, and so on. Therefore, the first participant is assigned to Group A, the second to Group B, the third to Group A, the fourth to Group B, the fifth to Group B, and the sixth to Group A.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, blinding is performed as a double-blind design. The patient (participant) and the outcome assessor (the individual measuring pain intensity using the VAS scale during follow-up days) are unaware of the type of intervention (dexamethasone or normal saline) received in each surgical side. However, the surgeon (performing the operation) is aware of the treatment allocation due to the nature of the intervention (impregnating the Gelfoam with the drug or saline during surgery); therefore, blinding of the surgeon is not feasible. In other words, the patient and the outcome assessor are blinded to the treatment allocation (double-blind).
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Zanjan University of Medical Sciences
Street address
Central Campus of Zanjan University of Medical Sciences, Sobuti Blvd., Zanjan, Iran
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Approval date
2026-06-16, 1405/03/26

Ethics committee reference number
IR.ZUMS.REC.1405.072

Health conditions studied

1

Description of health condition studied
Impacted third molar

ICD-10 code
K01.1

ICD-10 code description
Impacted teeth

Primary outcomes

1

Description
Postoperative pain intensity

Timepoint
Day 1, day 3, and day 7 after each surgical session

Method of measurement
Visual Analogue Scale (VAS), which is a 10-centimeter line ranging from 0 (no pain) to 10 (worst imaginable pain), and the patient marks their pain intensity on it.

2

Description
Number of analgesics consumed

Timepoint
First week after each surgical session

Method of measurement
Daily questioning of the patient about the number of analgesic tablets consumed in the past 24 hours and recording it on a designated form

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Intervention group: placement of a 1×1 cm piece of absorbable gelatin sponge (Gelfoam, Spongostan, Denmark) impregnated with 8 mg dexamethasone (8 mg vial, Caspian, Iran) dissolved in 2 ml normal saline into the tooth socket after extraction of impacted mandibular third molar. The socket is then closed with 3-0 silk suture. Both groups receive standard antibiotic (amoxicillin 500 mg every 8 hours) and oral analgesic (ibuprofen 400 mg as needed for pain).

Category
Treatment - Drugs

2

Description
Control group: placement of a 1×1 cm piece of absorbable gelatin sponge (Gelfoam, Spongostan, Denmark) impregnated with 2 ml normal saline (without drug) into the tooth socket after extraction of impacted mandibular third molar. The socket is then closed with 3-0 silk suture. Both groups receive standard antibiotic (amoxicillin 500 mg every 8 hours) and oral analgesic (ibuprofen 400 mg as needed for pain).

Category
Placebo

Recruitment centers

1

Recruitment center
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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
Zanjan 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
This is a general dentistry thesis with a limited sample size (35 patients) and a Split-mouth design. The data contains identifiable patient information. Due to confidentiality concerns and lack of appropriate infrastructure for data sharing at this level, there is no plan to share individual participant data. Furthermore, the study is funded by personal resources of the investigators, and no budget has been allocated for data preparation and sharing.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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