Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the Effect of Topical Dexamethasone in Alveolar Socket on Pain and Complications After Impacted third molar Tooth Surgery: Clinical trial

Protocol summary

Study aim
Evaluation of the Effect of Local Dexamethasone in the Tooth Socket on the Reduction of Pain and Postoperative Complications Following Surgical Removal of Impacted Mandibular Third Molars

Design
A randomized, double-blind, parallel, controlled clinical trial (Phase 3) conducted on 52 Patients.

Settings and conduct
Patients attending Baset Clinic in Khorramabad during the second half of 1404 will be randomly assigned to Intervention and Control Groups, with Permuted Block Randomization used within each Stratum. Both Patients and Evaluators are blinded, and the Code Breaker is a person external to the Research Team. After Surgery, a piece of Gel Foam containing 4 mg of Dexamethasone will be placed into the Tooth Socket in the Intervention Group and Sutured with 4-0 Nylon. In the Control Group, a Gel Foam soaked in Normal Saline will be placed in the Socket.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients aged 18 to 25 years without infection, who are not pregnant and do not have any life-threatening systemic diseases, without drug allergies to the medications used in the study, or recent use of antibiotics or anti-inflammatory drugs. Exclusion Criteria: Patients who cannot be followed up, whose healing process does not proceed normally, who use other anti-inflammatory or antibiotic drugs after surgery, or cases where the tooth of interest is close to the nerve canal.

Intervention groups
After the Surgical Extraction of the Impacted Third Molar and irrigation, a piece of Gel Foam impregnated with 4 mg of Dexamethasone will be placed into the Tooth Socket in the Intervention Group, followed by Suturing with 4-0 Nylon. In the Control Group, a piece of Gel Foam soaked in Normal Saline will be placed in the Socket.

Main outcome variables
Postoperative pain intensity; Postoperative swelling; Postoperative trismus

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20251029067813N1**
Registration date: **2025-11-07, 1404/08/16**
Registration timing: **prospective**

Last update: **2025-11-07, 1404/08/16**
Update count: **0**

Registration date
2025-11-07, 1404/08/16

Registrant information
Name
Zahra Joudaki
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 916 363 1904
Email address
zahra.joudakii@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-11-15, 1404/08/24
Expected recruitment end date
2026-01-20, 1404/10/30
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Effect of Topical Dexamethasone in Alveolar Socket on Pain and Complications After Impacted third molar Tooth Surgery: Clinical trial

Public title
Effect of topical Dexamethasone in the dental socket after surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18 to 25 years With Impacted third Mandibular Molars Without Pericoronitis or Infection Who are not Pregnant Have no life-threatening Systemic Disease No Allergy to the Drugs used in the Study No recent use of Antibiotics or Anti-inflammatory Drugs Who are willing to participate in the Study
Exclusion criteria:
Those whose Follow-up for recording Pain and Swelling was not possible Who were unwilling to continue in the Study Individuals whose Healing process was not normal Patients who used other Anti-inflammatory Drugs or Antibiotics after Surgery Whose Impacted third Molars were located close to the Nerve Canal
Age
From **18 years** old to **25 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, participants will be assigned to the intervention and control groups using stratified randomization. Stratification will be performed based on two variables: gender (male and female) and education level (below diploma, diploma, university), resulting in a total of six strata. Within each stratum, participants will be allocated using permuted block randomization with variable block sizes of four and six to maintain balance in the number of participants between the two groups. The random allocation sequence in each stratum will be generated and recorded by an independent biostatistician (who is not involved in the surgery or outcome assessment) using a table of random numbers and the statistical software International Business Machines Statistical Package for the Social Sciences (version 26). The unit of randomization will be the individual participant. To ensure allocation concealment, opaque, sealed, and sequentially numbered envelopes will be used. Each envelope will contain a card indicating the assigned treatment group (dexamethasone or placebo). The envelopes will be opened only at the time of surgery by a person who is not involved in the assessment process. Thus, both the participant and the outcome assessor will be blinded to the type of intervention, and the study will be conducted in a double-blind manner. The coded allocation list will be kept by an independent person outside the research team and will be opened only after the completion of data collection.
Blinding (investigator's opinion)
Double blinded
Blinding description
Neither the Patient nor the Evaluator has any information about the type of Treatment assigned to the Subjects. The Code Breaker is also a person outside the Research Team. Written Informed Consent will be obtained from all Patients for participation in the Study as well as for the Surgical Extraction of the Third Molar. However, the Patients will not be informed whether the administered Drug is Dexamethasone or Placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Lorestan University of Medical Sciences Ethics Committee
Street address
Eram Ave, west Goldasht sector
City
Khorram abad
Province
Lorestan
Postal code
6814785181
Approval date
2025-10-06, 1404/07/14
Ethics committee reference number
IR.LUMS.REC.1404.282

Health conditions studied

1

Description of health condition studied

The socket caused by impacted wisdom tooth surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain severity

Timepoint

The 2nd, 4th, and 7th Days After Surgery

Method of measurement

The Visual Analogue Scale will be used to measure the severity of patients' pain. The patient will be given a ten-centimeter ruler, numbered from 0 to 10, and the patient must indicate the level of pain on it on the second, fourth, and seventh days.

Secondary outcomes

1

Description

Facial swelling

Timepoint

The 2nd, 4th, and 7th days after surgery

Method of measurement

To measure swelling, we measure from the outer canthus of the eye to the mandibular protuberance, from the middle of the tragus of the ear to the outer corner of the lip on the same side in millimeter.

2

Description

Trismus severity

Timepoint

The 2nd, 4th, and 7th days after surgery

Method of measurement

We measure the distance between the edges of the upper and lower incisors in millimeters.

Intervention groups

1

Description

Intervention group: local anesthetic injection of inferior alveolar and long buccal nerve block with 2% lidocaine carpol containing epinephrine at 80000:1 will be performed, after which a sulcular incision and creation of a pocket flap will be made to expose the surgical area, and then the impacted wisdom tooth will be extracted. After that, the surgical area will be washed with 100 ml of normal saline, and in the next step, a piece of foam gel is soaked with 4 mg of dexamethasone manufactured by Iran Hormone Pharmaceutical Company and placed in the dental socket, and finally, it will be performed with a 04 nylon suture, then standard drug therapy with acetaminophen will be performed every 6 hours.

Category

Prevention

2

Description

Control group: for patients, local anesthesia injection of inferior alveolar and long buccal nerve block with 2% lidocaine carpol containing epinephrine at 80000:1 will be performed, after which a saccular incision and creation of a pocket flap will be made to expose the surgical area, after which the impacted wisdom tooth will be extracted. After that, the surgical area will be washed with 100 ml of normal saline, and in the next step, a piece of foam gel soaked in normal saline will be placed in the socket , then standard drug therapy with acetaminophen will be performed for patients every 6 hours. The normal saline used in this study will be manufactured by Samen Pharmaceutical Company, Mashhad, Iran.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Baset Dental Clinic, Khorramabad

Full name of responsible person

Dr Reza Nadripour Oral and maxillary Surgeon

Street address

Eram Av, West Goldasht sector

City

Khorram abad

Province

Lorestan

Postal code

6814785181

Phone

+98 916 363 1904

Email

Zahra.joudakii@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Reza Nadripour

Street address

Eram Av, West Goldasht sector

City

Khorramabad

Province

Lorestan

Postal code

6814785181

Phone

+98 916 363 1904

Email

Zahra.joudakii@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Reza Nadripour

Position

Oral and maxillary surgeon and professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Eram Ave, West goldasht sector

City

Khorramabad

Province

Lorestan

Postal code

6814785181

Phone

+98 916 363 1904

Email

Zahra.joudakii@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Reza Nadripour

Position

Oral and maxillary surgeon and professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Eram Ave, West goldasht sector

City

Khorramabad

Province

Lorestan

Postal code

6814785181

Phone

+98 916 363 1904

Email

Zahra.joudakii@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Reza Nadripour

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Eram Ave, West goldasht

City

Khorramabad

Province

Lorestan

Postal code

6814785181

Phone

+98 916 363 1904

Email

Zahra.joudakii@gmail.com

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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The data are backed up in a master file on the Lorestan University server. This file is password-protected and is only accessible to the researchers named in the Human Research Ethics Committee approvals. After the project is completed, identifying data will be removed from the record. These records will be retained permanently to be

used if the study is repeated with other drugs in the future. De-identified data may be made available to other researchers in the future to facilitate systematic reviews or meta-analyses. If such data are requested, they will only be made available after review and approval by the Human Research Ethics Committee.

When the data will become available and for how long

6 Months After Publication of the Results

To whom data/document is available

Researchers Affiliated with Academic and Scientific Institutions

Under which criteria data/document could be used

For the Completion of Research in the Same Field

From where data/document is obtainable

Zahra.joudakii@gmail.com

What processes are involved for a request to access data/document

Request from the Human Research Ethics Committee unit of Lorestan University of Medical Sciences and approval from that unit

Comments