

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of the effectiveness of ketorolac subperiosteal and infiltrate injections into the buccal mucosa in preventing postoperative complications after impacted third molar surgery.

Protocol summary

Study aim

Comparison of the effectiveness of ketorolac subperiosteal and infiltrate injections into the buccal mucosa in preventing postoperative complications after impacted third molar surgery..

Design

This study is a double-blind clinical trial. The study population includes all patients who refer to a private dental clinic in Kermanshah for wisdom tooth surgery. 84 eligible patients will be selected conveniently and randomly assigned to two intervention groups.

Settings and conduct

This study which will be conducted in private dental clinic of Kermanshah is double blinded one that The patient and physician evaluating the outcome will be kept blind to the exact injection site.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years, Physical health, Presence of an impacted molar confirmed by panoramic radiography and is free of infection and pericoronitis; No concomitant use of nonsteroidal anti-inflammatory drugs, salicylates, anticoagulants, anticonvulsants, and valproate due to interference with the injectable substance (ketorolac). Exclusion criteria: Recent use of anti-inflammatory drugs and antibiotics; Having underlying diseases such as diabetes, gastrointestinal diseases, etc; Current consumption of drugs, alcohol and opium over the past month; pregnant women

Intervention groups

The first intervention group will receive 30 mg of single-dose ketorolac (Alborz Pharmaceutical Company) as a subperiosteal injection immediately after anesthesia injection of the alveolar and lingual nerve blocks. The second intervention group will receive 30 mg of single-dose ketorolac (Alborz Pharmaceutical Company) as an infusion injection in the buccal mucosa immediately after injection of anesthesia of the alveolar and lingual nerve

blocks.

Main outcome variables

Pain intensity; Trismus; paresthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N155**

Registration date: **2020-11-18, 1399/08/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-18, 1399/08/28**

Update count: **0**

Registration date

2020-11-18, 1399/08/28

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-06, 1399/07/15

Expected recruitment end date

2020-12-10, 1399/09/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of ketorolac subperiosteal and infiltrate injections into the buccal mucosa in preventing postoperative complications after impacted third molar surgery.

Public title
Comparison of two ketorolac injection methods on complications after third tooth surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Physical health Presence of an impacted third molar is confirmed by panoramic radiography and is free of infection and pericoronitis No concomitant use of nonsteroidal anti-inflammatory drugs, salicylates, anticoagulants, anticonvulsants, and valproates due to interference with the injectable substance (ketorolac).
Exclusion criteria:
Recent use of anti-inflammatory drugs and antibiotics Having underlying diseases such as diabetes, gastrointestinal diseases, etc. Current consumption of drugs, alcohol and opium over the past month Pregnant women

Age
From **18 years** old to **40 months** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
The permutation random block is used for randomization. In this way, first, the total sample size and the ratio of sample size in groups are determined. Then, the number of samples will be selected from the table of random numbers of single-digit numbers between 0 and 9. For studies with two groups, the numbers 0-9 are divided into two equal blocks with a probability of assigning an individual to each block is 0.5. Block 4-0 for the first group and block 5-9 for the second treatment can be used. Based on the selected numbers from the table of random numbers and the determination of blocks, it is clear in which group each person who enters the study will be placed.

Blinding (investigator's opinion)
Double blinded

Blinding description

The patient and physician evaluating the outcome will be kept blind to the exact injection site.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-09-12, 1399/06/22

Ethics committee reference number

ir.kums.rec.1399.584

Health conditions studied

1

Description of health condition studied

Impacted teeth

ICD-10 code

K01

ICD-10 code description

Embedded and impacted teeth

Primary outcomes

1

Description

Pain intensity

Timepoint

Two and 7 days after dental surgery

Method of measurement

Based on visual pain scale

2

Description

Trismus

Timepoint

Two and 7 days after dental surgery

Method of measurement

Question from the patient (Low, medium, severe)

3

Description

Paresthesia

Timepoint

Two and 7 days after dental surgery

Method of measurement

Question from the patient (Low, medium, severe)

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group will receive 30 mg of single-dose ketorolac (Alborz Pharmaceutical Company) as a subperiosteal injection immediately after anesthesia injection of the alveolar and lingual nerve blocks.

Category

Treatment - Other

2

Description

The second intervention group will receive 30 mg of single-dose ketorolac (Alborz Pharmaceutical Company) as an infusion injection in the buccal mucosa immediately after injection of anesthesia of the alveolar and lingual nerve blocks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Personal clinic of Dr. Hamed Nazari

Full name of responsible person

Dr. Hamed Nazari

Street address

Dabira Azam Street, Arshia Building

City

Kermanshah

Province

Kermanshah

Postal code

6715813149

Phone

+98 83 3838 1541

Email

Nazari.hamed67@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Farid Najafi

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

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+98 83 3836 0014

Email

fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Mehrnaz Pourahmadi

Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

School of Dentistry, Shariati St.

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Province

Kermanshah

Postal code

6713954658

Phone

+98 83 3729 6591

Email

140dent95mehr@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Hamed Nazari

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

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Email

Nazari.hamed67@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Mehrnaz Pourahmadi

Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Email

140dent95mehr@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

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

Informed Consent Form

Yes - There is 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

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

3 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

Send E-mail to the responsible for the update to get the documentation

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

Documentation will be emailed within a 15-day timeframe

Comments