Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

comparison of the effect of Ketorolac and Betamethasone injection on post complications of third molar surgery (A clinical trial)

Protocol summary

Study aim
Comparison of the effect of preoperative betamethasone and ketorolac injection on postoperative pain, swelling and trismus

Design
Patients requiring mandibular third molar surgery are randomly divided into 2 intervention groups with equal number, gender, and similar severity. In each group, the anesthesia process will be performed with the same protocol and using perzocaine-E. Then 1mL of betamethasone LA or 30 mg of ketorolac is injected into the master muscle. Surgery is performed by the same surgeon in a dental office using a standard procedure appropriate to the type of incision. After work, patients are given the same painkillers (acetaminophen 325mg) and antibiotics (amoxicillin 500mg and metronidazole 250mg, one every 8 hours). Outcome assessment is performed before surgery, two days and 7 days after surgery. Patients in this study are blind.

Settings and conduct
Dr nazari dental clinic

Participants/Inclusion and exclusion criteria
Inclusion criteria: ages of 18 and 40, physical health (ASA I or II), the presence of a third mandibular molars whose occlusion is confirmed by panoramic radiography and free of infection and pericoronitis. Exclusion criteria: Concomitant use of antibiotics and nsaid drugs, salicylates, anticoagulants, anticonvulsants, and valproate . Consumption of fines for each of these substances in the past month (drugs, alcohol, opium, smoking) A person who has smoked at least two cigarettes a day in the past month, underlying diseases that interfere with wound healing such as systemic diseases such as diabetes, hypertension, Gastrointestinal diseases, kidney and lung disease, pregnancy, and any allergies to the drugs used in this study are surgical complications that are difficult to classify according to (Pell and Gregory classification Winter classification).

Intervention groups
1.KETOROLAC 2.BETAMETHASONE LA

Main outcome variables
PAIN ,SWELLING , TRISMUS

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191127045516N6**
Registration date: **2022-02-26, 1400/12/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-26, 1400/12/07**
Update count: **0**

Registration date
2022-02-26, 1400/12/07

Registrant information

Name
hamed Nazari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 83 3835 2842

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-24, 1400/12/05

Expected recruitment end date
2022-08-06, 1401/05/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effect of Ketorolac and Betamethasone injection on post complications of third molar surgery (A clinical trial)

Public title

comparison of the effect of Ketorolac and Betamethasone injection on post complications of third molar surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Physical health (ASA I or II) free of infection and pericoronitis. the presence of a third mandibular molars whose occlusion is confirmed by panoramic radiography age18 to 40 years old

Exclusion criteria:

Concomitant use of antibiotics and nonsteroidal anti-inflammatory drugs, salicylates, anticoagulants, anticonvulsants, and valprates is due to interaction with the injectable substance (ketorolac). Current use of any of these substances in the past month (drugs, alcohol, opium, smoking) Someone who has smoked at least two cigarettes a day in the past month Difficulty of surgery based on Pell and Gregory classification (Winter classification). allergies to the drugs used in this study Diseases that interfere with wound healing such as systemic diseases such as diabetes, hypertension, gastrointestinal diseases, kidney and lung and heart diseases, pregnancy.

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, the randomization block method with classification will be used. The classification will be based on gender and difficulty of surgery. Random sequencing will be performed by a statistical expert using Excel software with RANDOM function and Sort command in each class separately and codes A and B. To prevent the prediction of the last patient group in each block, blocks with different sizes of two, four and six in all classes will be used. Randomization will be considered for 40 patients in each class.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding will be done on one level, only the participant. Participants will not be able to identify the type of injectable drug because they will not be informed of the drug group to which they will belong. Patients are grouped through exactly the same envelopes containing the letters A or B. The physician is aware of the relationship between the letters and the drug, but patients are unaware. Patients will be informed about the drugs used in the trial before participating in the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Kermanshah University of Medical Sciences

Street address

SHAHID BEHESHTI Blvd

City

kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2022-02-08, 1400/11/19

Ethics committee reference number

IR.KUMS.REC.1400.801

Health conditions studied

1

Description of health condition studied

impacted teeth

ICD-10 code

K01.1

ICD-10 code description

Impacted teeth

Primary outcomes

1

Description

pain severity

Timepoint

second and seventh day after surgery

Method of measurement

visual analogue scale

2

Description
swelling
Timepoint
second and seventh day after surgery
Method of measurement
visual analogue scale

3

Description
trismus
Timepoint
the second and seventh day after surgery
Method of measurement
Maximum mouth opening limitation less than 35 mm

4

Description
surgery difficulty
Timepoint
before the surgery
Method of measurement
Using panoramic radiography based on tooth position angle, depth and position relative to Ramos mandible - Based on panoramic radiographic classification (Pell and Gregory classification, Winter classifocation) -

5

Description
patient general satisfaction
Timepoint
the second and seventh day after surgery
Method of measurement
visual analogue scale

6

Description
maximum mouth opening
Timepoint
beofre the surgery and second and seventh day after surgery
Method of measurement
interincisal distance between mandibular and maxillary central teeth

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: A single intramuscular injection of 3mg betamethasone LA in 1mL (manufactured by Exir Pharmaceutical Company) in the master muscle immediately after injection of 2% lidocaine anesthesia.
Category
Prevention

2

Description
Intervention group 2: A single intramuscular injection of 30 mg in 1 mL of ketorolac (manufactured by Exir Pharmaceutical Company) in the master muscle immediately after injection of 2% lidocaine anesthesia.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Nazari Dental Clinic
Full name of responsible person
Dr Hamed Nazari
Street address
Dabirazam St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Reza Khodarahmi
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research_it@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
Hamed Nazari

Position
Assistant proffesor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Shariati St.Dentistry School.

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Student

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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