

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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)

##### Phone

+98 83 3835 2842

##### Email address

hamed.nazari@kums.ac.ir

##### 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 age 18 to 40 years old  
**Exclusion criteria:**  
Concomitant use of antibiotics and nonsteroidal anti-inflammatory drugs, salicylates, anticoagulants, anticonvulsants, and valproates 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 classification) -

## 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**

before 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.

##### **City**

Kermanshah

##### **Province**

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##### **Postal code**

6713737364

##### **Phone**

+98 83 3729 3520

##### **Email**

Nazari.hamed67@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Kermanshah University of Medical Sciences

##### **Full name of responsible person**

Reza Khodarahmi

##### **Street address**

Shahid beheshti Blvd.

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##### **Email**

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 professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dentistry  
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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**  
Parnian Tarabosi  
**Position**  
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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