

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Comparison of the effectiveness of ketorolac injection into the masseter and medial pterygoid muscles in preventing the post-operative complications after mandibular third molar surgery

#### Protocol summary

##### Study aim

Comparison of the effectiveness of ketorolac injection into the masseter and medial pterygoid muscles in preventing the post-operative complications after mandibular third molar surgery

##### Design

randomized double blinded Clinical trial, parallel groups, phase 2 on 84 patients. Randomisation was done by generating random numbers using Excel software.

##### Settings and conduct

Patients in need of mandibular third molar surgery are randomly divided into 2 groups with equal numbers. In each group, the anesthesia process will be done with the same protocol using Persocaine-E. Then 30 mg ampoule of Ketorolac Trometamine is injected into the masseter or internal pterygoid muscle. The surgery is done by the same surgeon using the standard method according to the type of impaction in the dental clinic. After that, patients are given analgesics (acetaminophen 325mg) and antibiotics (amoxicillin 500mg and metronidazole 250mg, number: 20, one every 8 hours) in the same way. Outcome assessment is done before surgery, 2 and 7 days after surgery. Patients and outcome assessors are blind in this study.

##### Participants/inclusion and exclusion criteria

Inclusion: 1-ASA I or II 2-presence of a confirmed impacted mandibular third molar with no infection and pericoronitis 3- patient is ready to sign the testimonial. Exclusion: 1-History of underlying diseases 2-current consumption of drugs, alcohol, opioids 3-smoking 4-recent consumption of anti-inflammatory drugs and antibiotics 5-pregnant women 6- any allergies

##### Intervention groups

group 1: injection of 30 mg ampoule of Ketorolac Trometamine into the masseter muscle immediately after anesthesia. group 2: injection of 30 mg ampoule of

Ketorolac Trometamine into the internal pterygoid muscle immediately after anesthesia.

##### Main outcome variables

severity of pain, swelling, Paresthesia, General satisfaction, Trismus, Maximum opening of mouth, surgery difficulty level, number of analgesics taken

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191127045516N2**

Registration date: **2020-12-15, 1399/09/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-12-15, 1399/09/25**

Update count: **0**

##### Registration date

2020-12-15, 1399/09/25

##### 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

2020-11-10, 1399/08/20

##### Expected recruitment end date

2021-01-19, 1399/10/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effectiveness of ketorolac injection into the masseter and medial pterygoid muscles in preventing the post-operative complications after mandibular third molar sugrery

**Public title**

Comparison of the effectiveness of ketorolac injection into the masseter and medial pterygoid muscles in preventing the post-operative complications after mandibular third molar sugrery

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

ASA I or II health status. presence of a impacted mandibular third molar confirmed by a panoramic image absence of the mandibular third molar infection and pericoronitis The patient is ready to take part in the study and sign the testimonial

**Exclusion criteria:**

History of underlying diseases affecting the wound healing process like systemic diseases(diabetes,high blood pressure,gastrointestinal system diseases,kidney disorders,heart and lung diseases) current consumption of drugs,alcohol,opiums(consumption of any of these substances during the last month) smoking(someone who has smoked at least two cigarettes a day during the last month) recent consumption of anti- inflammatory drugs and antibiotics pregnant women any allergies or Hypersensitivities to the drugs used in this study

**Age**

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

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **84**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Based on the random allocation law,Random numbers are generated using Excel software by a statistician.to do this,three-digit codes are generated and the last digit on the right indicates the patient group.if the number obtained is odd(1,3,5,7,9),the patient is in the internal pterygoid muscle injection group and if the number is even(0,2,4,6,8),the patient is in the masseter muscle injection group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

participants and outcome assessor are blinded in this study.as the ketorolac injection is done after the anesthesia,patient will not know the exact location of the injection(masseter or internal pterygoid muscle)and will not be informed.also the outcome assessor will not be informed which muscle was injected.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

patients who have bilateral surgery have at least 15-days interval between each surgery and are admitted to study for only one surgery.

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Kermanshah University of Medical Sciences

**Street address**

Ethics Committee, Department of Research and Technology, Central Building, Shahid Beheshti Boulevard, Kermanshah

**City**

kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Approval date**

2020-09-12, 1399/06/22

**Ethics committee reference number**

IR.KUMS.REC.1399.607

**Health conditions studied**

**1**

**Description of health condition studied**

severity of pain

**ICD-10 code**

G89.1

**ICD-10 code description**

Acute pain, not elsewhere classified

**2**

**Description of health condition studied**

Trismus

**ICD-10 code**

G71.8

### **ICD-10 code description**

Other primary disorders of muscles

### **3**

#### **Description of health condition studied**

swelling

#### **ICD-10 code**

R22.9

#### **ICD-10 code description**

Localized swelling, mass and lump, unspecified

### **4**

#### **Description of health condition studied**

paresthesia

#### **ICD-10 code**

R20

#### **ICD-10 code description**

Disturbances of skin sensation

## **Primary outcomes**

### **1**

#### **Description**

severity of pain

#### **Timepoint**

before surgery,2 and 7 days later

#### **Method of measurement**

Visual Analogue Scale(VAS)

### **2**

#### **Description**

swelling

#### **Timepoint**

2 and 7 days after surgery

#### **Method of measurement**

Visual Analogue Scale(VAS)

### **3**

#### **Description**

General satisfaction

#### **Timepoint**

2 and 7 days after surgery

#### **Method of measurement**

Visual Analogue Scale(VAS)

### **4**

#### **Description**

Trismus

#### **Timepoint**

2 and 7 days after surgery

#### **Method of measurement**

Restrictions on opening the mouth(mild,moderate,severe)

### **5**

#### **Description**

paresthesia

#### **Timepoint**

2 and 7 days after surgery

#### **Method of measurement**

yes/no

### **6**

#### **Description**

Maximum opening of the mouth

#### **Timepoint**

before surgery,2 and 7 days later

#### **Method of measurement**

by a ruler(0-50 millimetre)

### **7**

#### **Description**

Number of analgesics taken

#### **Timepoint**

2 and 7 days after surgery

#### **Method of measurement**

number(0-100)

### **8**

#### **Description**

difficulty of the surgery

#### **Timepoint**

Before surgery

#### **Method of measurement**

according to panoramic radiograph based on spatial direction,depth and ramus relationship(easy,moderate,difficult)

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group 1: injection of 30 mg ampoule of Ketorolac Tromethamine in to the masseter muscle immediately after anesthesia injection.

#### **Category**

Prevention

### **2**

#### **Description**

Intervention group 2: injection of 30 mg ampoule of Ketorolac Tromethamine in to the internal pterygoid muscle immediately after anesthesia injection.

#### **Category**

Prevention

## **Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Dr Nazari Dental clinic

**Full name of responsible person**

Hamed Nazari

**Street address**

Dabiraezam st.

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Kermanshah

**Province**

Kermanshah

**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**

Farid Najafi

**Street address**

Vice Chancellor for Research and Technology,  
Kermanshah University of Medical Sciences, Shahid  
Beheshti Blvd

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**Province**

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**Phone**

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**Fax****Email**

faridnajafi@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**

Hadis Yari

**Position**

Under graduated student of Dentistry

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

The school of Dentistry, shariati St.

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### Person responsible for scientific 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 updating data

#### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

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**Position**

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**Province**

Kermanshah

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h.yari7493@gmail.com

**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