

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Evaluating the effect of injection of ketorolac or dexamethasone into the ptrygomandibular space on pain and swelling following removal of third mandibular molar

#### Protocol summary

##### Study aim

Evaluating the effect of injection of ketorolac or dexamethasone into the ptrygomandibular space on pain and swelling following removal of lower third mandibular molar

##### Design

Randomized clinical trial using randomization method with sample size of 60, blind, phase 2

##### Settings and conduct

The population of patients referring to Kerman University of Medical Science, Dentistry Faculty in order to have a surgery to remove their impacted wisdom tooth or third molar (M3) are randomly divided into two groups. After injecting the anesthetic substance, one of the two materials is injected into petrigom andibuler space. Before commencing on the surgery, a ruler is used to measure the mouth opening right from the tip of incisor teeth. After the surgery, a check list designed based on VAS criteria is used to document the patients' pain and discomfort right after the surgery, one, three and six hours after the surgery and finally on a daily basis. This process continues for one week. After a week, the mouth opening measurement is done once again for every patient. The number of times and the time each patient has used the painkiller is also recorded.

##### Participants/Inclusion and exclusion criteria

The subjects entering this study include all those patients in need of one-sided Third Molar (M3) surgery, with the age of more than 18 years, and a weight lower than 100 kg and be in the category of ASA 1, 2. the patients who have used painkiller 24 hours before treatment and who have shown sensitivity toward the injected medicines or have received more than three anesthetic injection.

##### Intervention groups

A group that receives dexamethasone. A group that receives ketorolac

##### Main outcome variables

Severity of pain, severity of discomfort, oral opening, side effects, pain reliefs, Intervals between pain relief

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180910040981N1**

Registration date: **2019-04-09, 1398/01/20**

Registration timing: **retrospective**

Last update: **2019-04-09, 1398/01/20**

Update count: **0**

##### Registration date

2019-04-09, 1398/01/20

##### Registrant information

##### Name

Saeed Hajmohammadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3211 8071

##### Email address

hajmohammadi@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-07, 1397/07/15

##### Expected recruitment end date

2019-01-20, 1397/10/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluating the effect of injection of ketorolac or dexamethasone into the pterygomandibular space on pain and swelling following removal of third mandibular molar

**Public title**

Evaluating the effect of injection of ketorolac or dexamethasone on pain and swelling following removal of third molar

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients enter the study after obtaining written consent. All patients are over 18 years of age The weight of all patients is below 100kg, Depending on the category of American Anesthesia Association in the ASA group one and two. Both groups require the treatment of one-sided low-grade third molars

**Exclusion criteria:**

Patients who have taken medication or sedation 24 hours before treatment Patients who have a history of allergy to dexamethasone or ketorolac Patients who receive more than 3 local anesthetic injections during the surgical procedure

**Age**

From **18 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, 60 identical sheets (30 sheets for Dexamethasone and 30 sheets for Ketorolac) are deposited in a container and the sheets are randomly removed without replacement from the container. And it continues until all the papers are taken.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Only a nurse is aware of the type of injectable drug. The surgeon and the patient are unaware of the injected medication and the nurse gives the medication to surgeon.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of kerman University of Medical Sciences

**Street address**

Haft Bagh Alavi Blv

**City**

Kerman

**Province**

Kerman

**Postal code**

7618759689

**Approval date**

2018-11-13, 1397/08/22

**Ethics committee reference number**

IR.KMU.REC.1397.248

**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 and discomfort severity

**Timepoint**

Immediately after surgery, 1, 3 and 6 hours later, and eventually on a daily basis for one week.

**Method of measurement**

Visual Analog Scale

**Secondary outcomes**

empty

**Intervention groups****1****Description**

First intervention group:After anesthetic injection, 30 ml of Ketorolac is injected once before surgery

**Category**

Treatment - Drugs

## 2

### Description

Intervention group: After anesthetic injection, 8 ml of Dexamethasone is injected once before surgery

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Dental School of Kerman

**Full name of responsible person**

Saied Hajmohammadi

**Street address**

ShafaBlv

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**Phone**

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**Email**

dentistryschool@kmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr.Abbas Pardakhti

**Street address**

Shafa Blvd

**City**

Kerman

**Province**

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**Email**

hajmohamadisaeed@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kerman 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**

Kerman University of Medical Sciences

**Full name of responsible person**

Saeed Hajmohamadi

**Position**

Associate

**Latest degree**

Specialist

**Other areas of specialty/work**

Maxillofacial Surgery

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**Email**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Saeed Hajmohammadi

**Position**

Associate

**Latest degree**

Specialist

**Other areas of specialty/work**

Maxillofacial Surgery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Saeed Hajmohamadi

**Position**

Associate

**Latest degree**

Specialist

**Other areas of specialty/work**

Maxillofacial Surgery

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available