

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of submucosal injection of Ketorolac versus Dexamethasone on postoperative pain after third molar surgery: A randomized clinical trial

#### Protocol summary

##### Study aim

This study aimed to clarify the possible role of two preoperative analgesics, either dexamethasone (4 mg) or ketorolac (30 mg) administered 10 minutes before surgery, in clinical recovery after third molar surgery.

##### Design

This clinical trial has a control group with parallel randomized double-blind groups that was performed on 60 patients in the second phase. Random numbers were used for randomization.

##### Settings and conduct

this study was performed in Afzal Clinic in Isfahan, all by a same maxillofacial surgeon. The method of this study was completely under the supervision of the student and the professor related to this project. The blinding of this study was by coding the syringes and preparing them in such a way that neither the nurse nor the doctor had any news item.

##### Participants/Inclusion and exclusion criteria

All the patients were >16 years of age and ASA I or II. All the patients have at least one impacted mandibular third molar detected by a panoramic radiograph. The impacted teeth categorized as class II relationship, position 'B' angulation. Patients who have not taken any painkillers a week before surgery. The patient should not have any infection or pain or other medical problems in the week before surgery. People who have not taken any painkillers a week before surgery.

##### Intervention groups

The patients in group K received 1 mL of Ketorolac (30 mg) sublingually. The patients in group D received 1 mL of Dexamethasone (4 mg) sublingually. The patients in group C received 1 mL of Normal Saline sublingually.

##### Main outcome variables

It seems that injectable Ketorolac can have good analgesic effects to reduce patients' pain for up to 7 hours. Dexamethasone reduces pain on average up to 11 hours after surgery. Also, the use of analgesics in these two groups is less than the control group

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180906040960N1**

Registration date: **2021-06-16, 1400/03/26**

Registration timing: **retrospective**

Last update: **2021-06-16, 1400/03/26**

Update count: **0**

##### Registration date

2021-06-16, 1400/03/26

##### Registrant information

##### Name

farhad mardani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 3322 8507

##### Email address

farhad73mardani@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-11, 1397/08/20

##### Expected recruitment end date

2019-05-21, 1398/02/31

##### Actual recruitment start date

2018-11-11, 1397/08/20

##### Actual recruitment end date

2019-05-21, 1398/02/31

##### Trial completion date

2019-06-20, 1398/03/30

##### Scientific title

Effect of submucosal injection of Ketorolac versus Dexamethasone on postoperative pain after third molar surgery: A randomized clinical trial

#### Public title

Effect of Dexamethasone and Ketrolac on postoperative pain

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients must be over 16 years old. Patients who according to the category ASA are in group 1 or 2. People who have not taken any painkillers a week before surgery. The patient should not have any infection or pain or other medical problems in the week before surgery. All the patients have at least one impacted mandibular third molar detected by a panoramic radiograph. The impacted teeth categorized as class II relationship, position 'B' angulation.

##### Exclusion criteria:

Patient who has not any gastrointestinal diseases. Impacted tooth has no symptom. Procedure prolonged more than 30. The patient is pregnant or breastfeeding. The patient has a physical or mental disability. Patient with a history of allergies or contraindications for nonsteroidal anti-inflammatory drugs. During the study period, the patient develops a complication that interferes with his treatment. The patient is taking medication due to a disease.

#### Age

From **16 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider

#### Sample size

Target sample size: **60**

Actual sample size reached: **55**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The randomization method of this study was simple. The randomization unit of this study is personal. Sixty patients who were eligible to participate in the study were assigned a multi-digit random number obtained by using a random number table and then the numbers were placed in a bag. The numbers were removed from the bag and placed in the Ketorolac, Dexamethasone and control groups, respectively. These random numbers were also pasted on insulin syringes. On the day of surgery, the patient receives a pre-filled insulin syringe and gives it to the surgeon to perform the concealment properly.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

After selecting the patients, the drugs that were already

labeled and had a special code were given to the nurse. The nurse took the medicine in a special syringe and gave it to the therapist. Therapists and nurses were unaware of the type of drug because the color and volume of the substances in all three groups were similar. The nurse then recorded the special code on a piece of paper.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice-chancellor in research affairs-medical university of Isfahan

##### Street address

No.8174673461, Hezar Jerib St., Isfahan University of Medical Sciences, Faculty of Dentistry, Isfahan Town, Iran

##### City

Isfahan

##### Province

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##### Postal code

8174673461

#### Approval date

2019-05-07, 1398/02/17

#### Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.142

## Health conditions studied

### 1

#### Description of health condition studied

Pain intensity and number of analgesics used by patients after impacted mandibular third molar surgery

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Pain intensity in patients in Ketorolac group

#### Timepoint

Measurement of patients' pain intensity before surgery and after surgery with an interval of one hour until 12 hours after surgery.

#### Method of measurement

VAS

## 2

### **Description**

Pain intensity in patients in Dexamethasone group

### **Timepoint**

Measurement of patients' pain intensity before surgery and after surgery with an interval of one hour until 12 hours after surgery.

### **Method of measurement**

VAS

## 3

### **Description**

Pain intensity of group patients in control

### **Timepoint**

Measurement of patients' pain intensity before surgery and after surgery with an interval of one hour until 12 hours after surgery.

### **Method of measurement**

VAS

## 4

### **Description**

Number of Analgesics in the Ketorolac group

### **Timepoint**

Immediately after surgery up to 72 hours after surgery

### **Method of measurement**

Number of pills by day

## 5

### **Description**

Number of Analgesics in Dexamethasone group

### **Timepoint**

Immediately after surgery up to 72 hours after surgery

### **Method of measurement**

Number of pills by day

## 6

### **Description**

Number of analgesics used in the control group

### **Timepoint**

Immediately after surgery up to 72 hours after surgery

### **Method of measurement**

Number of pills by day

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: "group K" received 1ml ketorolac 30 mg

#### **Category**

Treatment - Drugs

## 2

### **Description**

Intervention group 2: "group D" received 1ml dexamethasone 4mg

### **Category**

Treatment - Drugs

## 3

### **Description**

Control group: "Group C" received 1ml normal saline as placebo.

### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Afzal clinic

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

Darius Hasheminia

##### **Street address**

First corner, Soroush St., Ahmad Abad Sq., Isfahan Town

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Esfahan University of Medical Sciences

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

Ramin Mosharaf dehkordi

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#### **Grant name**

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

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dariush Hashemina

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**

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**Position**

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**Latest degree**

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## Sharing plan

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

Yes - There is 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**

Yes - There is a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Informed consent - Patient questionnaire and SPSS data

**When the data will become available and for how long**

Access started from 2023

**To whom data/document is available**

Consultant Professor and Supervisor

**Under which criteria data/document could be used**

The data can only be used for evaluation and verification

**From where data/document is obtainable**

Applicants can use the data and information only with the coordination of the tutor

**What processes are involved for a request to access**

**data/document**

The required information will be provided to the applicants for one week at their discretion

**Comments**