Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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 1or 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
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Isfehan
Province
Isfehan
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
Dariush 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 Hasheminia
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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