

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Evaluation of the premedication effect of Ketorolac compared to Ibuprofen in pain control after mandibular third molar surgery: a randomized clinical trial

Protocol summary

Study aim

Determining the effect of ketorolac premedication compared to ibuprofen in pain control after mandibular third molar surgery

Design

Randomized clinical efficacy, with parallel groups intervention group and control group, phase 3 study on 78 samples

Settings and conduct

Based on the inclusion criteria, 78 samples of patients requiring mandibular third molar tooth surgery referred to the special clinic of Birjand Faculty of Dentistry are selected; They will be randomly divided into 2 intervention groups and 1 control group. 1 hour before surgery, the first intervention group will be given 400 mg of ibuprofen, the second intervention group will be given 20 mg of ketorolac, and the control group will receive a placebo. Then, using a visual analog scale, the amount of pain is measured in 1, 2, 4, 6, 8, 12, 24 hours.

Participants/Inclusion and exclusion criteria

Entry conditions: indication for mandibular wisdom tooth surgery with mesioangular, horizontal and vertical orientation of Winter classification and class I,II and position A and B of Pell and Gregory classification
Conditions of non-entry: prohibition of non-steroidal anti-inflammatory drugs (allergy to them, patients with coronary artery bypass surgery, pregnancy, presence of active peptic ulcer and kidney failure.)

Intervention groups

The first intervention group received 400 mg ibuprofen, the second intervention group received ketorolac 20 mg, and the control group received a placebo.

Main outcome variables

intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230621058554N1**

Registration date: **2024-01-16, 1402/10/26**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-16, 1402/10/26**

Update count: **0**

Registration date

2024-01-16, 1402/10/26

Registrant information

Name

Narges Gholami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3272 9750

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-27, 1402/10/06

Expected recruitment end date

2024-06-04, 1403/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the premedication effect of Ketorolac compared to Ibuprofen in pain control after mandibular third molar surgery: a randomized clinical trial

Public title

Effect of ketorolac in wisdom tooth surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Written consent to participate in the research project
Indication of mandibular wisdom tooth surgery with mesioangular, horizontal and vertical orientation of Winter and class I, II and position A and B of Pell and Gregory classification
Age 18 to 35 years
Consciousness, cooperation and ability to use medicine and not to use other analgesic medicine

Exclusion criteria:

Contraindication to the use of non-steroidal anti-inflammatory drugs (allergy to them, patients with coronary artery bypass surgery, pregnancy, presence of active peptic ulcer and kidney failure.)
Drug use
1) Indications of mandibular wisdom tooth surgery with distangular and transverse orientation of winter and class III ,position C of Pell and Gregory classification

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be allocated using 6 permutation blocks whose order is generated by R software and with the blockrand command, in fact each block contains two letters A, two letters B and two letters is c.)

Blinding (investigator's opinion)

Double blinded

Blinding description

A person outside the study codes the capsules and a code is assigned to each patient. Until the end of the study, the researcher and the participant in the study will not know which category they are in.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Birjand University of Medical Sciences

Street address

Ghafari Ave , Birjand University of Medical Sciences

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2023-12-20, 1402/09/29

Ethics committee reference number

IR.BUMS.REC.1402.402

Health conditions studied

1

Description of health condition studied

Mandibular third molar surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

intensity of pain

Timepoint

1,2,4,6,8,12,24 hours after surgery

Method of measurement

via Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving a single dose of 400 mg oral ibuprofen tablets from Hakim Pharmaceutical Company (produced in the form of identical capsules under sterile conditions) along with 200 ml of water 1 hour before surgery

Category

Treatment - Drugs

2

Description

Intervention group: receiving a single dose of 20 mg oral

ketorolac tablets from Aburihan Pharmaceutical Company (produced in the form of identical capsules under sterile conditions) along with 200 ml of water 1 hour before surgery.

Category

Treatment - Drugs

3**Description**

Control group: receiving a single dose of placebo (similar to other capsules produced in sterile conditions) along with 200 ml of water 1 hour before surgery

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Birjand Faculty of Dentistry Special Clinic

Full name of responsible person

Mostafa Alizadeh Abkoh

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

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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

Birjand 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**

Birjand University of Medical Sciences

Full name of responsible person

Mostafa Alizadeh Abkoh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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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