Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)
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+98 56 3272 9750
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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 updating data

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Birjand University of Medical Sciences
Full name of responsible person
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Student
Latest degree
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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