Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative Assessment of the Effect of Ibuprofen and ketorolac on Edema Trismus and Pain after lower Third Molar Surgery

Protocol summary

Study aim

Comparative Assessment of the Effect of Ibuprofen and ketorolac on Edema Trismus and Pain after lower Third Molar Surgery

Design

This study is a prospective double-blind clinical trial

Settings and conduct

Twenty male and female patients aged 16 to 35 years selected from candidates of impacted wisdom teeth surgery in Shahid Sadoughi Faculty of Dentistry (Yazd, Iran). The patient underwent surgery to remove a lower left or right third molar in a treatment session depending on the type of drug being used and the side of surgery selected at random. All surgeries will be performed in the morning and under local anesthesia (lidocaine + epinephrine). Two medication are prepared by the pharmacist so that neither the surgeon, nor the student, nor the patient are aware of the contents of each package, and will randomly give one of the packages coded by the pharmacist

Participants/Inclusion and exclusion criteria

Inclusion criteria include: age between 16 and 35 years of age with any systemic disease; lack of any local lesions including cysts or odontogenic tumors (dependent or non-dependent on the third molar) ,trauma to the area or any signs of inflammation (pericoronitis) or infection Any medication, especially anti-inflammatory drugs, 3 days prior to surgery. No history of NSAIDs (ibuprofen or ketorolac). Lack of any conditions including impaired immunity (including one year's history of chemotherapy, use of immunosuppressants). No pregnancy or lactation at the time of surgery

Intervention groups

Ibuprofen: A type of NSAID with sedative and fever properties that is mainly used in the clinic due to its proven efficacy and reliability compared to similar drugs. Ketorolac: a potent non-steroidal anti-inflammatory and moderate anti-inflammatory drug. This drug is a non-selective cox inhibitor and thus a blocker of prostaglandin production.

Main outcome variables

pain, Edema,Trismus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191014045101N1**
Registration date: **2020-01-19, 1398/10/29**
Registration timing: **prospective**

Last update: **2020-01-19, 1398/10/29**
Update count: **0**

Registration date

2020-01-19, 1398/10/29

Registrant information

Name

Mostafa Gavahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3625 6975

Email address

mgdds@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-25, 1398/11/05

Expected recruitment end date

2020-02-24, 1398/12/05

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative Assessment of the Effect of Ibuprofen and ketorolac on Edema Trismus and Pain after lower Third Molar Surgery

Public title
Comparative Assessment of the Effect of Ibuprofen and ketorolac on Edema Trismus and Pain after lower Third Molar Surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1) Age between 16 and 35 years 2) Any systemic disease of any body organ such as anemia, epilepsy, diabetes, hypertension, hyperthyroidism, osteoporosis or digestive disease, addicts and alcoholics who put surgery at risk Either inhibits the administration of the drug or makes it difficult to repair the surgical area 3) The presence of any localized lesions including odontogenic cysts or tumors (dependent or non-dependent on the third molar) trauma to the area or any signs of inflammation (pericoronitis) or Infection 4) No use of any drug, especially anti-inflammatory drugs 3 days before surgery 5) No history of NSAID sensitivity (ibuprofen or ketorolac) 6) Lack of any conditions that may include impaired immunity (including one year's history of chemotherapy, use of immunosuppressants)
Exclusion criteria:
1) Patients who have only one tooth extracted and who have not been referred to the opposite tooth for surgery 2) Patients who have not taken their medication as prescribed 3) Patient non-cooperation
Age
From **16 years** old to **35 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple Randomization Using Random Allocation Software, Individual Randomization Unit Random Allocation Software Randomization Tool, How to Build Random Sequence Randomization Software, Explanation of Drug Coded by Dr Pharmacist, and When giving the medicine to the patient, the pharmacist is asked what medication code to give to the patient.
Blinding (investigator's opinion)
Double blinded
Blinding description
The two types of drugs studied include ibuprofen 200 mg and ketorolac 10 mg (Caspian Pharmaceuticals) in capsules apparently similar to those prepared by the pharmacist so that neither the surgeon, the student, nor the patient were aware of the contents of each package. Randomly, one of the packets that is coded by the pharmacist will be given to the patient
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yazd Faculity of DENTISTRY
Street address
Yazd,dahe fajr Blvd
City
YAZD
Province
Yazd
Postal code
8914881167
Approval date
2019-07-27, 1398/05/05
Ethics committee reference number
IR.SSU.REC.1398.091

Health conditions studied

1

Description of health condition studied
Mandibular Impacted Teeth Surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Edema Trismus and Pain
Timepoint
Before surgery and 2 and 7 days after surgery
Method of measurement
In the post-treatment period, pain ratings will be assessed by reporting pain scores on an 11-point visual Analogue scale by patients at 6, 12, and 24 hours after surgery. Edema assessment is performed by measuring

intervals such as the interval between the tip of the chin to the lower edge of the ear fins and the mandibular tooth line before and 2 and 7 days after surgery. Evaluation of mouth opening will be done by measuring the maximal distance between the incisal edges of the anterior teeth before and 2 and7 days after surgery

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Ibuprofen Consumer: Ibuprofen 200 mg (Caspian Pharmaceutical Company) Two medicines in capsules that are apparently similarly prepared by the pharmacist so that neither the surgeon nor the student nor the patient The contents of each packet will be randomly assigned to one of the packets coded by the pharmacist. Patients will be advised to take one of these capsules when the pain begins after surgery. Afterwards, take the capsule every 6 hours for two days

Category
Treatment - Drugs

2

Description
Intervention group: Ketorolac Consumer: Ketorolac 10 mg (Caspian Pharmaceutical Company) Two medicines in capsules that are apparently similarly prepared by the pharmacist so that neither the surgeon nor the student nor the patient The contents of each packet will be randomly assigned to one of the packets coded by the pharmacist. Patients will be advised to take one of these capsules when the pain begins after surgery. Afterwards, take the capsule every 6 hours for two days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
بخش جراحی دانشکده دانداپزشکی شهید صدوقی یزد

Full name of responsible person
دکتر مصطفی گواهی

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
DR.MASOUD MIRZAEI

Street address
Faculty of Dentistry - Imam Khomeini St. - Yazd - Dental Fajr Boulevard

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mmirzaie@ssu.ac.ir

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Grant name
Shahid Sadoughi University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
DR.MOSTAFA GAVAHI

Position
Assistant Professor

Latest degree
Specialist
Other areas of specialty/work
Maxillofacial surgeon
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Web page address
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
MOSTAFA GAVAHI
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
AIDA PAYDAR
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