

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 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)

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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 Faculty of DENTISTRY

Street address

Yazd, dahe fajr Blvd

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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 and 7 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 دندانپزشکی 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

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

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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<https://web.ssu.ac.ir/>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

MOSTAFA GAVAHI

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Assistant professor

Latest degree

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Other areas of specialty/work

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

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AIDA PAYDAR

Position

Student

Latest degree

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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