

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

comparative evaluation of preemptive analgesic effect of diclofenac and ketorolac in oral form after third molar surgery

Protocol summary

Study aim

Comparison of the effect of diclofenac and ketorolac drugs orally after impacted wisdom tooth surgery on pain relief

Design

Clinical trial without control group, With intervention groups only, Randomized, Phase 2 on 52 patients, A table of random numbers is used for randomization.

Settings and conduct

This study will be performed on 52 patients in the maxillofacial surgery department of Ahwaz Dental School, Written consent is obtained from patients before the study, The impacted wisdom teeth are mesiangular or according to the Pell & Gregory classification, Patients will be divided into two equal groups of 26 based on a series of random numbers. Patients in group A will receive ketorolac 10 mg tablets orally and patients in group B will receive Diclofenac 25 mg tablets orally, and the drugs will be given 1 hour before surgery. The visual analog scale is used to assess postoperative pain by telephone on the day of surgery and on the second, third and seventh day after surgery. This study lacks blinding.

Participants/Inclusion and exclusion criteria

Written consent is obtained from patients prior to the study. Inclusion criteria, patients without systemic disease and non-regular use of medication : Exclusion criteria, patients with contraindications to NSAIDs such as allergies, asthmatic patients, pregnant or lactating.

Intervention groups

Patients will be divided into two equal groups of 26 based on a series of random numbers. Patients in group A will receive 25 mg diclofenac and patients in group B will receive 10 mg of ketorolac, and the drugs will be given orally 1 hour before surgery.

Main outcome variables

Measurement of patients' pain during the study period with drug treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220116053738N1**

Registration date: **2022-04-11, 1401/01/22**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-11, 1401/01/22**

Update count: **0**

Registration date

2022-04-11, 1401/01/22

Registrant information

Name

Zahra Hatami

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-11, 1401/01/22

Expected recruitment end date

2022-05-05, 1401/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparative evaluation of preemptive analgesic effect of diclofenac and ketorolac in oral form after third molar surgery

Public title

Evaluation of analgesics after impacted wisdom tooth surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with systemic health

Exclusion criteria:

Patients with contraindications to non steroidal anti-inflammatory drugs such as allergies, asthma patients, pregnant or lactating patients are excluded from the study

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 52

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple randomization is performed using a table of random numbers. To use the table, first the method of reading the table numbers is determined and then the numbers are intended for study groups and is recorded. For example, even numbers are considered for intervention A and odd numbers are considered for intervention B. These sequences are created using SAS software and studied based on them.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی اهواز

Street address

Nazanin Residential Complex, Shahrivar St, between Dey and Bahman St. Golestan neighborhood, Ahwaz

City

Ahvaz

Province

Khouzestan

Postal code

6136746746799

Approval date

2021-10-31, 1400/08/09

Ethics committee reference number

IR.AJUMS.REC.1400.467

Health conditions studied

1

Description of health condition studied

Comparison of the effect of diclofenac and ketorolac on pain relief after surgery

ICD-10 code

K01.1

ICD-10 code description

Impacted teeth

Primary outcomes

1

Description

Measurement of pain after impacted wisdom tooth surgery with drug treatment

Timepoint

In the study "Measuring the amount of pain after impacted wisdom tooth surgery with medication", the amount of pain is measured on the first day of surgery and 2, 3, 7 days after taking the drug.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1:The members of this group use 10 mg oral Ketorolac tablets of Abu Reihan company one hour before the surgery. and then how to take the pills, once every 6 hours, The duration of this study is 7 days.

Category

Treatment - Surgery

2

Description

Intervention group 2:The members of this group use 25 ml oral diclofenac tablets of Abu Reihan company one hour before the surgery. and then how to take the tablets, once every 6 hours. In total, and then how to take the pills once every 6 hours, The duration of this study is 7 days.

Category

Treatment - Surgery

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

Ahvaz Dental School

Full name of responsible person

Dr Mahdis MasoudRad

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Dental School, Dey Ave ,Golestan Town

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

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi Moghadam

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Zahra Hatami

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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

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Full name of responsible person

Dr Mahdis Masoud Rad

Position

Associate 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

Zahra Hatami

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)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Part of the data, such as information about the main outcome, can be shared.

When the data will become available and for how long

Access starts 3 months after the results are published.

To whom data/document is available

Only for researcher working in academic and scientific institutions

Under which criteria data/document could be used

There are no conditions and all colleagues can use all the data

From where data/document is obtainable

Dr Zahra hatami phone number 09165423859 Email address zahrahatami1997@gmail.com

What processes are involved for a request to access data/document

Finally one week after requesting data or documentation

Comments