

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparison the prophylactic effect of Indomethacin and Diclofenac Sodium in reducing pain after surgical removal of mandibular horizontal impacted third molar

Protocol summary

Study aim

Comparison of the effect of indomethacin and diclofenac prophylaxis in reducing pain after mandibular horizontal third molar surgery.

Design

Clinical trial with two parallel groups, triple blind, randomized, phase 2 and 3 on 90 patients.

Settings and conduct

The questionnaire form will be given to all people in the study. The information of the first stage of the questionnaire will be completed. This form will include demographic information and, in addition, measure the pain level of the person after third molar tooth surgery. Pain after dental surgery will be recorded by Visual Analogue Scale (VAS) based on the pain ruler. This study will be conducted in Resalat Clinic and Sadaf Clinic of Shahrekord Dental School in 1401.

Participants/Inclusion and exclusion criteria

Inclusion criteria Patients' satisfaction with participating in the study Patients aged 18-35 years mandibular horizontal impacted third molar Exclusion criteria Dissatisfaction of patients to continue the study Those who have used ketorolac

Intervention groups

They will be randomly divided into one of two groups, A and B, using the permutation block method, in one group of the painkiller indomethacin and in the other group, the painkiller diclofenac sodium tablet will be used as a pain prevention drug. Then, each person will be given one of the two types of drugs of group A or B, 30 minutes before the dental surgery.

Main outcome variables

The group under review Age sex Pain 6 hours after surgery Pain 12 hours after surgery Pain 24 hours after surgery Drug side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221004056088N1**

Registration date: **2022-10-15, 1401/07/23**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-15, 1401/07/23**

Update count: **0**

Registration date

2022-10-15, 1401/07/23

Registrant information

Name

Babak Hasanalizad mazhar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-08, 1401/07/16

Expected recruitment end date

2022-11-07, 1401/08/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the prophylactic effect of Indomethacin and Diclofenac Sodium in reducing pain after surgical removal of mandibular horizontal impacted third molar

Public title

Comparison the effect of Indomethacin and Diclofenac Sodium in reducing pain after surgical removal of mandibular third molar

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients' satisfaction with participating in the study
Patients' satisfaction with participating in the study
mandibular horizontal impacted third molar
Patients without gastrointestinal ulcer
Not taking painkillers or other drugs for 24 hours before surgery
Not having a history of addiction to drugs or painkillers
Patients who are not pregnant or breastfeeding.
Known insensitivity to common non-steroidal anti-inflammatories and analgesics
No history of nasal polyps, bronchospasm or angioedema caused by non-steroidal anti-inflammatory drugs.
People who are able to take medicine orally.

Exclusion criteria:

Dissatisfaction of patients to continue the study
Those who have used ketorolac

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

They will be randomly divided into one of two groups, A and B, using the permutation block method, in one group of the painkiller indomethacin (Aria Pharmaceutical Company, Tehran, Iran) (75 mg)) and in the other group, the painkiller diclofenac sodium tablet (Alborz Pharmaceutical Company, Qazvin, Iran) (100 mg) will be used as a pain prevention drug. Then, each person will be given one of the two types of drugs of group A or B, 30 minutes before the dental surgery. The study will be conducted in a triple-blind manner

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study will be conducted in a triple-blind manner so that blinding will be established for the maxillofacial specialist doctor, statistical analyst and volunteer patients. The blinding of the specialist doctor is done in such a way that the drugs will be given to the specialist doctor by his assistant, without his knowledge of the

type of drug, in the same boxes named with A and B. On the other hand, to blind the patient, he will be told that he will be given one of the two drugs, indomethacin or diclofenac sodium, randomly and without his knowledge of its type. In order to blind the statistical analyst, the information will be provided to him in the form of two groups B and A, where the type of drug in each group is not known, and the result will be checked.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

mellate gharbi

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8817858935

Approval date

2022-10-04, 1401/07/12

Ethics committee reference number

IR.SKUMS.MED.REC.1401.038

Health conditions studied

1

Description of health condition studied

pain after surgical removal of mandibular horizontal impacted third molar

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

Pain 6 hours after surgery and pain 12 hours after surgery and pain 24 hours after surgery

Method of measurement

The level of pain expressed by patients after horizontal third molar surgery

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group A will use indomethacin tablet painkiller as a pain prevention drug.

Category

Prevention

2

Description

Intervention group: Intervention group B will use the painkiller diclofenac sodium tablet as a pain prevention drug.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sadaf Clinic, Shahrekord Faculty of Dentistry

Full name of responsible person

Babak Hasanalizadmazhar

Street address

blue square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Arsalan Khaledifar

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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

Shahre-kord University of Medical Sciences

Proportion provided by this source

50

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

Shahre-kord University of Medical Sciences

Full name of responsible person

Babak Hasanalizadmazhar

Position

student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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