

# 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

+98 21 5622 7033

##### Email address

info@skums.ac.ir

##### 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

##### City

Shahrekord

##### Province

Chahar-Mahal-va-Bakhtiari

##### Postal code

8817858985

##### Phone

+98 38 3222 4320

##### Email

gooooonaz75@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahre-kord University of Medical Sciences

##### Full name of responsible person

Arsalan Khaledifar

##### Street address

Rahmatiyeh

##### City

Shahrekord

##### Province

Chahar-Mahal-va-Bakhtiari

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8817853685

#### Phone

+98 38 3226 0869

#### Email

info@skums.ac.ir

#### 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

Dentistry

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Elahieh

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##### Province

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2222222222

##### Phone

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##### Email

gooooonaz75@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahre-kord University of Medical Sciences

##### Full name of responsible person

Alireza Tamizifar

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry  
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Kashani Avenue  
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galex9494@gmail.com

## Person responsible for updating data

### 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**  
Dentistry  
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**City**  
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**Province**  
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**Postal code**  
1964814311  
**Phone**  
009832224320  
**Email**  
goolnaz75@gmail.com

## 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