

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of prophylactic effect of single-dose Celecoxib and Mefenamic acid in reducing pain after tooth extraction

Protocol summary

Study aim

Find and identify the best medicine to reduce pain after tooth extraction

Design

Clinical trial without control group, with parallel groups, three-way blind, randomized, phase 3-2 on 150 patients. The permutation block allocation method will be used for randomization.

Settings and conduct

This study will be performed in Resalat Dental Clinic of Shahrekord University of Medical Sciences and on clients who need a simple tooth extraction. Participants do not know the exact name of the drug used and also the researcher and statistical expert receive information in the form of two groups A and B and the study is a three-way blind.

Participants/Inclusion and exclusion criteria

Patients over 14 years of age and of any sex who do not have a serious systemic disease and are in class 1 or 2 (ASA) will be included in this study. Patients who referred for periodontal support for tooth extraction will not be included in the study. Patients with symptoms of infection will also not be included in the study. Patients who need analgesics for any reason other than the desired toothache will not be included in the study. Patients who have a history of taking any analgesia up to 12 hours before tooth extraction will not be included in this study. Patients with severe physical and mental illness are not included in the study. Patients who require severe surgical intervention will not be included in this study.

Intervention groups

Participants in this study will be randomly divided into two equal groups. One group will be given celecoxib 30 minutes before tooth extraction and the other group will be given mefenamic acid 30 minutes before tooth extraction. All patients will not use any other medication or sedatives for up to 6 hours after tooth extraction.

Main outcome variables

Pain after tooth extraction; Drug used to create a prophylactic effect on pain; Patient comfort after tooth extraction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220407054442N1**

Registration date: **2022-07-30, 1401/05/08**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-30, 1401/05/08**

Update count: **0**

Registration date

2022-07-30, 1401/05/08

Registrant information

Name

Amin Samimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3781 6798

Email address

amin1samimi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-01, 1401/04/10

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of prophylactic effect of single-dose Celecoxib and Mefenamic acid in reducing pain after tooth extraction

Public title
Comparison of prophylactic effect single-dose Celecoxib and Mefenamic acid

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients over 14 years and of any sex who do not have a serious systemic disease and are classified in class 1 or 2 of The American Society of Anesthesiologists (ASA) will be included in this study.
Exclusion criteria:
 Patients who referred for tooth extraction due to periodontal support problem will not be included in the study. Patients with symptoms of infection such as swelling, fever, pus discharge, and decreased mouth opening will also not be included in the study. Patients who need analgesics for any reason other than toothache will not be included in the study. Patients who have a history of taking any painkillers up to 12 hours before tooth extraction will not be included in this study. Patients with systemic physical or mental illness or at risk for infectious endocarditis, coagulation problems, local and systemic infections, known allergies to celecoxib or mefenamic acid, a history of asthma, or drug or alcohol addiction will not be included in this study. Patients who require severe surgical intervention to extract a tooth will not be included in this study. celecoxib is contraindicated in patients with heart problems. Therefore, patients with heart disease will not participate in this study.

Age
From **14 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done by permutation blocks with the size of each block equal to 6. The randomization list is provided by Random Allocation software There will be a person who is not among the collaborators of the project and does not know about the content of the interventions. Medicines in two categories A and B are

given to the patient. In addition, the patient is told that one of the two studied drugs will be given to him, but it will not be clear which of the two drugs will be given to him. The obtained results will be presented to the statistical expert in the form of two groups A and B. Therefore, in this study, the operator, the patient and the statistical expert are blinded.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient is told that one of the two drugs celecoxib or mefenamic acid will be given at random to relieve and prevent pain after tooth extraction. On the other hand, the assistant of the agent will randomly give one of these two drugs, which are in the same boxes and named as A and B and their type is unknown, to the patient, without informing the group type to the agent. Reports will be given to the statistical expert in the form of two groups A and B.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Shahrekord University of Medical Sciences

Street address

No. 9, Azeen borje building, Andisheh Blvd, Farhangian Town

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8818618926

Approval date

2022-06-28, 1401/04/07

Ethics committee reference number

IR.SKUMS.REC.1401.068

Health conditions studied

1

Description of health condition studied

Tooth extraction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score in Visual Analogue Scale score questionnaire

Timepoint

Measure the amount of pain in one, three and six hours after tooth extraction

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Patients that receiving a single dose of celecoxib 200 mg capsules

Category

Treatment - Drugs

2

Description

second intervention group: Patients receiving a single dose of Mefenamic acid 250 mg capsules

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Resalat Dental Clinic of Shahrekord University of Medical Sciences

Full name of responsible person

Milad alikhani

Street address

Resalat Chaleshtar Dental Clinic, Rahbar Blvd.

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8815713471

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international@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

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Street address

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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

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

Shahre-kord University of Medical Sciences

Full name of responsible person

Amin Samimi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Fax**Email**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Informed Consent Form

No - There is not 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

All information of the participants, including: age, gender, type of tooth extracted, type of medication used before tooth extraction, amount of pain felt by the person, date and time of the operation, is available after the person is not identified.

When the data will become available and for how long

Access starts 6 months after the results are published.

To whom data/document is available

The data of this study is available only for researchers working in academic and scientific institutions and students studying in these centers.

Under which criteria data/document could be used

There are the following conditions for the benefit of individuals authorized to use the information published by this study: Be a member of researchers working in academic and scientific institutions or a student studying in these centers. The use of the information of this study for reference as well as review studies is unimpeded.

From where data/document is obtainable

Applicants can apply for information in the following ways: Email to: amin1samimi@gmail.com Refer to the research department of Shahrekord University of Medical Sciences

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

In order to access the information of this study, the applicant should send an e-mail to amin1samimi@gmail.com and if he does not receive a response within 7 working days, he should refer to the research department of Shahrekord University of Medical Sciences to receive the information.

Comments