Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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.
City
Shahrekord
Province
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Postal code
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
Milad alikhani
Street address
Resalat Chaleshtar Dental Clinia, Rahbar Blvd.
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international@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
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
Street address
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Person responsible for updating data

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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