

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of preemptive analgesic effect of Naproxen, Celecoxib and Acetaminophen codeine on pain control after mandibular third molar surgery in patients to dentistry clinic of bushehr university of medical sciences

Protocol summary

Study aim

The purpose of this study was to compare the analgesia effect of naproxen, celecoxib and acetaminophen codeine on pain control after third molar extraction of mandibular molars and the feasibility of replacement of non-steroidal anti-inflammatory drugs, an inhibitor of COX-2.

Design

This study was a blind, parallel, randomized, and controlled double-blind clinical trial in 72 patients referred to the dental clinic of Bushehr University of Medical Sciences. Patients were randomly divided into 3 groups, each group received 250 mg naproxen, 100 mg of celecoxib and 325 mg of acetaminophen codeine for half an hour before surgery.

Settings and conduct

The location of the study was a dental clinic at Bushehr University. The drugs were insulated into light and temperature insulated glasses and encoded under sterile gamma-ray lab conditions and were not known to Surrey, neither patients nor surgeons of the type of medication. Delivery of the drug to the patient and follow up of the patient's condition by someone other than the surgeon. The drug was used on the label of the drug.

Participants/Inclusion and exclusion criteria

A graph to confirm that the third molar is the same, the pain rating on the patient - the patient does not have a history of systemic diseases - the patient does not have a history of allergic to steroid drug - Avoid at least 48 hours before taking an analgesic drug - The patient is able to read and understand the checklist.

Intervention groups

A total of 72 patients aged 18-40 years old referred to the dental clinic of Bushehr University of Medical Sciences in 1998-97 were evaluated to compare the analgesic effects of celecoxib, naproxen and

acetaminophen codeine.

Main outcome variables

Record the pain, the time and the total number of consumable painkillers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190615043899N1**

Registration date: **2019-07-16, 1398/04/25**

Registration timing: **retrospective**

Last update: **2019-07-16, 1398/04/25**

Update count: **0**

Registration date

2019-07-16, 1398/04/25

Registrant information

Name

Seyed mehdi Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-05-31, 1398/03/10
Actual recruitment start date
2019-02-20, 1397/12/01
Actual recruitment end date
2019-05-16, 1398/02/26
Trial completion date
2019-05-16, 1398/02/26

Scientific title

Comparison of preemptive analgesic effect of Naproxen, Celecoxib and Acetaminophen codeine on pain control after mandibular third molar surgery in patients to dentistry clinic of bushehr university of medical sciences

Public title

Comparison of preemptive analgesic effect of Naproxen, Celecoxib and Acetaminophen codeine on pain control after mandibular third molar surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient OPG to confirm that the hardness of the lower third molar is the same. Patient-patient pain rating History of systemic diseases Patient should not have a history of hypersensitivity to steroid drugs Patient in the range of 18 to 60 years old Avoid taking an hour before taking analgesic A person can read and understand the checklist The patient does not take analgesic because of chronic pain

Exclusion criteria:

There is an infection of the postoperative dry socket Diabetic patients Systemic drug interactions with the three drugs in this study Use of psychological drugs The presence of rotting teeth or needing treatment in the mouth Lack of cooperation for future referrals Systemic disease People who had started treating the wound of the gastrointestinal tract for 30 days before surgery Used analgesics or another drug for 24 hours before surgery History of narcotic or analgesic addiction Patients who were pregnant or Breastfeeding Known sensitivity to anti-inflammatory drugs, non-steroidal anti-inflammatory drugs ordinary or cyclooxygenase-2 inhibitors

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **78**

Actual sample size reached: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into three groups of 24 patients using randomized block method. According to random

block allocation method, first, the volume of each block is determined, in this study, 12 blocks of 6 blocks were determined. After the block list was prepared, a number was allocated to each block. Then, random numbers were chosen between 1 and 12, and the random allocation list was selected according to the order of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The way of blinding was this: the drugs were embedded in insulating glasses of light and temperature and encoded under sterile gamma rays under laboratory conditions. The sample code was revealed after the study was completed and the results were revealed. Delivery of the drug to the patient and follow up of the patient's condition by someone other than the surgeon. The method of administration of the drug on the label of the drug was determined to be patient; who took the drug for three days according to the instructions, ie, naproxen 250 mg every 6 hours, celecoxib 100 mg every 12 hours and acetaminophen 325 mg every 6 hours.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Bushehr University of Medical Sciences

Street address

No. 1, Line 332, Deadlock 4, Imam Blvd

City

Bushehr

Province

Boushehr

Postal code

75167-96479

Approval date

2019-02-18, 1397/11/29

Ethics committee reference number

IR.BPUMS.REC.1397.113

Health conditions studied

1

Description of health condition studied

Control of pain after third molar surgery

ICD-10 code

XIX

ICD-10 code description

Injury, poisoning and certain other consequences of external causes

Primary outcomes

1

Description

The severity of pain

Timepoint

The severity of pain was the patient who was recorded in the questionnaire during the prescribed hours (7 days and 72, 48, 24, 12, 8, 4)

Method of measurement

The severity of pain was as follows: the patient, based on her sense of pain, determined a number between 10-1 according to the definition of the pain states based on the degree of discomfort / pain. The number 1 indicates that the patient feels good and does not feel pain, and the number 10 indicates a painful pain, to the extent that the patient leaves all his work and feels the need for rest.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In this study, acetaminophen codein was used as a standard dose (control) to evaluate the efficacy of other drugs; So, half an hour before, surgery was given to a group of acetaminophen 325 mg.

Category

Treatment - Drugs

2

Description

Intervention group: Half an hour before surgery, naproxen 250 mg (Pars Dara Company) was given by this group.

Category

Treatment - Drugs

3

Description

Intervention group: Half an hour before surgery, another group took 100 mg celecoxib (Darupakhsh, Tehran).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Clinic of Bushehr University of Medical Sciences

Full name of responsible person

Seyed Mehdi Hosseini

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Bushehr University of Medical Sciences, Dental Clinic, Shahid Heidari St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

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Grant name

Deputy of Research of Bushehr University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Boushehr 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

Boushehr University of Medical Sciences

Full name of responsible person

Seyed Mehdi Hosseini

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as the key outcome information or the like, can share

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Not allowed

From where data/document is obtainable

Dr seyed mehdi hosseini pmn.hsn30067@gmail.com

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

A week after the request

Comments