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 givenby this group.
Category
Treatment - Drugs

3

Description
Intervention group: Half an hour before surgery, another group took100 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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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
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Other areas of specialty/work
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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
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