

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of celecoxib versus acetaminophen as pre-emptive analgesics for the management of post operative pain after impacted mandibular third molar surgery

Protocol summary

Study aim

To evaluate the effectiveness of oral celecoxib over oral acetaminophen as pre-emptive analgesic for pain control after impacted mandibular third molar surgery, thus identifying the group of drugs that is more effective to achieve pre-emptive analgesia.

Design

Randomized Controlled clinical trial with a parallel group design of 70 patients, enrolled between 18th February 2021 to 18th August 2021 and followed for 6 months

Settings and conduct

Department of Oral and Maxillofacial Surgery, AFID, Rawalpindi.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients of both gender with age range 17-50 years, Patients with at least one impacted mandibular third molar that is indicated for surgical extraction, Patients with no intake of analgesic and anti-inflammatory drugs for 1 week. Exclusion criteria: Pregnant or nursing women. Patients with serious diseases like liver, kidney and cardiovascular diseases. Patients with ulcers or bleeding in the digestive tract. Patients who are unable to express subjective discomfort symptoms. Patients with periodontal disease involving the adjacent teeth.

Intervention groups

Intervention group is more efficacious as pre-emptive analgesic for post-operative pain control, in terms of mean pain reduction and low intake dose of rescue analgesic, after impacted mandibular third molar surgery.

Main outcome variables

The mean post-operative pain score at 4, 6 and 8 hours was 5.60 ± 1.29 , 5.34 ± 1.16 and 5.66 ± 1.26 for group A (oral acetaminophen) versus 3.0 ± 1.24 , 2.97 ± 1.10 and 2.86 ± 1.22 for group B (oral celecoxib) (p-value = 0.0001). The mean Ibuprofen consumption (number of

tablets) within 24 hours was 2.40 ± 0.88 for group A (oral acetaminophen) versus 0.97 ± 0.66 for group B (oral celecoxib) (p-value = 0.0001).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230714058773N4**

Registration date: **2023-10-10, 1402/07/18**

Registration timing: **retrospective**

Last update: **2023-10-10, 1402/07/18**

Update count: **0**

Registration date

2023-10-10, 1402/07/18

Registrant information

Name

Tehmina Maryam

Name of organization / entity

Armed forces institute of dentistry, combined military hospital, Rawalpindi, Pakistan

Country

Pakistan

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+92 333 9576737

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-18, 1399/11/30

Expected recruitment end date

2021-08-18, 1400/05/27

Actual recruitment start date

2020-06-01, 1399/03/12

Actual recruitment end date

2021-08-18, 1400/05/27

Trial completion date

2021-08-18, 1400/05/27

Scientific title

Comparison of celecoxib versus acetaminophen as pre-emptive analgesics for the management of post operative pain after impacted mandibular third molar surgery

Public title

Comparison of celecoxib versus acetaminophen as pre-emptive analgesics for the management of post operative pain after impacted mandibular third molar surgery

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Male and female aged from 17 to 50 years old Patients with at least one impacted mandibular third molar that is indicated for surgical extraction and also confirmed by periapical radiographs including mesioangular, distoangular, horizontal and vertical impactions Patients with no intake of analgesic and anti-inflammatory drugs for 1 week.

Exclusion criteria:

Patients with conditions in which the use of NSAIDs and COX-2 inhibitors is contraindicated. Patients with serious diseases like liver, kidney and cardiovascular diseases Pregnant or nursing women Patients with ulcers or bleeding in the digestive tract. Patients who are unable to express subjective discomfort symptoms. Patients with periodontal disease involving the adjacent teeth

AgeFrom **17 years** old to **50 years** old**Gender**

Both

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **75**Actual sample size reached: **75****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of armed forces institute of dentistry CMH Rawalpindi

Street address

Range road Rawalpindi

City

Rawalpindi

Postal code

46000

Approval date

2021-12-21, 1400/09/30

Ethics committee reference number

905/Trg-ABP1K2

Health conditions studied**1****Description of health condition studied**

Third molar surgery

ICD-10 code

K01.1

ICD-10 code description

Impacted teeth

2**Description of health condition studied**

Pain

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

3**Description of health condition studied**

Celecoxib

ICD-10 code

Y45.3

ICD-10 code description

Other nonsteroidal anti-inflammatory drugs [NSAID]

Primary outcomes**1****Description**

Pain

Timepoint

30 minutes before intervention and 4,6,8 hours after intervention

Method of measurement

The visual analogue scale comprised a horizontal line, 10cm in length with word descriptors at each endpoint, 0 at the left end presenting "no pain" and point 10 at the right end representing "worst possible pain."

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:35 patients received an oral dose of 200 mg of Celecoxib 30 minutes before surgery. All operations were performed by the same surgeon and the efficacy of both drugs were evaluated by the same surgeon. Patients were educated properly on how to record their pain intensity on the visual analogue scale by placing a vertical mark across the horizontal line of the VAS at the point they felt the pain at 4, 6 and 8 hours after surgery. Each patient revisited for follow up with their records of pain at 4, 6 and 8 hours after surgery and total number of tablets consumed within 24 hours.

Category

Treatment - Drugs

2

Description

Control group:35 patients received an oral dose of 500 mg of acetaminophen 30 minutes before surgery. All operations were performed by the same surgeon and the efficacy of both drugs were evaluated by the same surgeon. Patients were educated properly on how to record their pain intensity on the visual analogue scale by placing a vertical mark across the horizontal line of the VAS at the point they felt the pain at 4, 6 and 8 hours after surgery. Each patient revisited for follow up with their records of pain at 4, 6 and 8 hours after surgery and total number of tablets consumed within 24 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Armed forces institute of dentistry CMH ,Rawalpindi ,Pakistan

Full name of responsible person

Tehmina Maryam

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Range road Rawalpindi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Armed forces institute of dentistry CMH Rawalpindi

Full name of responsible person

Muhammad Nazir Khan

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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

Armed forces institute of dentistry CMH Rawalpindi

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

Armed forces institute of dentistry CMH Rawalpindi

Full name of responsible person

Tehmina Maryam

Position

Registrar

Latest degree

Bachelor

Other areas of specialty/work

Oral and maxillofacial surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Registrar

Latest degree

Bachelor

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Position

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable