Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 crieteria: 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 crieteria: 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) ver us 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

Phone

+92 333 9576737

Email address

tehminamaryam@hotmail.com

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
Age
From **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
Celecoxeb
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 Celecoxeb 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 urgery. 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 urgery. 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
Street address
Range road Rawalpindi
City
Rawalpindi
Postal code
46000
Phone
+92 333 9576737
Email
tehminamaryam27@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Armed forces institute of dentistry CMH Rawalpindi
Full name of responsible person
Muhammad Nazir Khan
Street address
Range road Rawalpindi
City
Rawalpindi
Postal code
46000
Phone
+92 333 2353267
Email
nazeerkhan996@gmail.com
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
Street address
Range road Rawalpindi
City
Rawalpindi
Province
Punjab
Postal code

46000

Phone
+92 333 9576737

Email
Tehminamaryam27@gmail.com

Person responsible for scientific 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

Street address
Armed forces institute of dentistry CMH Rawalpindi

City
Rawalpindi

Province
Punjab

Postal code
46000

Phone
+92 333 9576737

Email
Tehminamaryam27@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Armed forces institute of dentistry CMH Rawalpindi

Full name of responsible person
Tehmina Maryam

Position
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Latest degree
Bachelor

Other areas of specialty/work
Oral and maxillofacial surgery

Street address
Armed forces institute of dentistry CMH Rawalpindi

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Tehminamaryam27@gmail.com

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