Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Comparing the analgesic effect of single-dose preoperative administration of noblegin, celecoxib and advalgin ER on demand for next dose of analgesic in mandibular third molar surgery

Protocol summary

Study aim

Comparing the analgesic effect of preoperative administration of noblegin,celecoxib & advalgin ER on demand for postoperative analgesic use in mandibular third molar surgery

Design

A triple blind,parallel group& placebo control clinical trial study on 120 healthy patients aged 15 to 29 years.A dose of the study drugs & placebo is given to the patient 30 minutes pre surgery.Iboprufen 400 mg is prescribed as a rescue drug for all groups.It is recommended that patients use painkillers if they experience moderate to severe pain(VAS≥4).Random allocation 0.2 software will be used for randomization.

Settings and conduct

In the Tuba Sari Dental Clinic,surgerys will be performed on healthy patients candidated for wisdom tooth surgery aged 15 to 29 years old. The patient, the surgeon and the analyst will be unaware of the type of analgesic (triple blinded).

Participants/Inclusion and exclusion criteria

Inclusion criteria:ASA class I patients Candidated for prophylactic removal of mandibular third molar,full or partial bony impaction confirmed by panoramic X-ray; Requiring soft tissue flap,bone manipulation & bone removal. Non inclusion criteria:Smokers; Pregnant or breastfeeding women or women of child bearing potential not using adequate contraception; Allergy or hypersensitivity to study or rescue medication or any other nsaids,opioids and acetyl salicylic acid; History of NSAID-sensitive asthma.

Intervention groups

Intervention group1:a pre-operative dose of 330 mg Nobelgin tablets Intervention group2:a pre-operative dose of 600 mg Advalgin ER coated tablet Intervention group3:a pre-operative dose of 200 mg celecoxib capsules Control group:a pre-operative dose of placebo

Main outcome variables

The number of patients needing analgesics; the time of the first analgesic consumption; the total number of analgesic use; the post surgery pain level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221207056746N1**
Registration date: **2023-05-31, 1402/03/10**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-31, 1402/03/10**
Update count: **0**

Registration date

2023-05-31, 1402/03/10

Registrant information

Name

zohre mozoun

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3335 6194

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yasaman.mozoun@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-02, 1401/08/11

Expected recruitment end date

2023-08-01, 1402/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the analgesic effect of single-dose preoperative administration of noblegin, celecoxib and advalgin ER on demand for next dose of analgesic in mandibular third molar surgery

Public title

Comparison of the analgesic effect of three analgesics before surgery in pain after mandibular wisdom tooth surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy patients (ASA class I) Candidates of prophylactic removal of mandibular third molar,full or partial bony impaction confirmed by panoramic X-ray Requiring soft tissue flap, bone manipulation and bone removal No medication consumption in the past 21 days The presence of the first and second molars Good oral hygiene Absence of pericoronitis or inflammation signs Absence of local or systemic infection

Exclusion criteria:

Smokers Pregnant or breastfeeding women or women of child bearing potential not using adequate contraception Allergy or hypersensitivity to study treatments, rescue medication (rm) or any other nsaids, opioids and acetyl salicylic acid History of NSAID-sensitive asthma History of or the suspicion of drug or alcohol abuse Apical radiolucent image in target tooth Consmuption of central nervous system depressants Pre-existing pain and acute inflammation Inability to understand or perform the study procedure Psychosis Consumption of caffeine-containing beverages, chocolate, or alcohol within 4 hours prior to surgery Oral contraception use Being in the menstrual period Any contraindication of cox-2 inhibitors use

Age

From **15 years** old to **29 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization (blocks of size 4); Individual. Randomization tool: random allocation software 2; How to make a random sequence and how to hide it: Using the software, codes A and B will be generated, where code A means applying the intervention group and code B means applying the control group for each person. Finally, the codes will be placed in the sealed envelope and the number of each patient will be written on the envelope. As each patient enters, the doctor will open the envelope and apply the desired treatment

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients, surgeon, data collector and biometrician will be unaware of the analgesic treatment (triple blind design). Medications and palcebo will be given to patients in dark matte jars of one color by the assistant before surgery so only the assistant is aware of the type of medicine.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Third floor; Mozoun 20 building, Bustan1, Pasdar alley,Imam square

City

Sari

Province

Mazandaran

Postal code

4815837614

Approval date

2022-12-24, 1401/10/03

Ethics committee reference number

IR.MAZUMS.REC.1401.430

Health conditions studied

1

Description of health condition studied

postoperative pain

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description
postoperative pain intensity
Timepoint
4hours & 7 hours postsurgery,the first day and the third day after surgery
Method of measurement
Visual Analogue Scale

2

Description
the time of first analgesic intake
Timepoint
one week after surgery
Method of measurement
Referring to document

3

Description
The number of patients who needed analgesics (vas≥4)
Timepoint
One week after surgery
Method of measurement
Referring to patients' documents

4

Description
the total number of analgesics used
Timepoint
One week after surgery
Method of measurement
Referring to patients' documents

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: pre-operative consumption of one Nobelgin tablet manufactured by Pars Daru Pharmaceuticals, each tablet contains acetaminophen 300 mg, caffeine 15 mg and codeine 15 mg
Category
Treatment - Drugs

2

Description
Intervention group 2: pre-operative consumption of a 600 mg Advalgin AR coated tablet containing 200 mg ibuprofen in quick-release form and 400 mg in extended release form, manufactured by Abidi Pharmaceuticals
Category
Treatment - Drugs

3

Description
Intervention group 3: pre-operative consumption of one 200 mg celecoxib capsule, manufactured by Elixir Pharmaceuticals
Category
Treatment - Drugs

4

Description
Control group: pre-operative consumption of one placebo tablet (starch)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sari Tuba dentistry clinic
Full name of responsible person
Amirhossein Moaddabi
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Khazar square
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4815837614
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
superviser & sari dental school
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
Mazandaran University of Medical Sciences
Full name of responsible person
Amirhossein Moaddabi
Position
Assistant Professor
Latest degree
Specialist
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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

it is not planned yet

When the data will become available and for how long

it is not planned yet

To whom data/document is available

it is not planned yet

Under which criteria data/document could be used

it is not planned yet

From where data/document is obtainable

it is not planned yet

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

it is not planned yet

Comments

it is not planned yet