

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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. Ibuprofen 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 ( $VAS \geq 4$ ). Random allocation 0.2 software will be used for randomization.

##### Settings and conduct

In the Tuba Sari Dental Clinic, surgeries 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 nsaid, 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

##### Email address

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 nsoids, 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 Consumption 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 placebo 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 $\geq$ 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

##### **Street address**

Khazar square

##### **City**

Sari

##### **Province**

Mazandaran

##### **Postal code**

4815837614

##### **Phone**

+98 11 3335 6194

##### **Email**

yasaman.mozoun@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Mazandaran University of Medical Sciences

##### **Full name of responsible person**

amirhossein moaddabi

##### **Street address**

Sari Dental school,next to Tubi Clinic,Khazar Blvd,Sari

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https://mazums.ac.ir/

**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
No  
**Title of funding source**  
supervisor & 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  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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**Other areas of specialty/work**  
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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