Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Comparing the preventive effect of celecoxib on pain after ankle fracture surgery

Protocol summary

Study aim
Determining the effect of prophylactic administration of celecoxib on pain after ankle fracture surgery

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 55 patients. A table of random numbers will be used for randomization.

Settings and conduct
After obtaining informed consent, patients over 18 years of age who are candidates for ankle fracture orthopedic surgery will be studied in the operating room of Imam Hossein (AS) Hospital. People with uncontrolled underlying diseases, treated with drugs that affect pain, suffering from neuropathy, history of allergic reactions to NSAIDs, suffering from mental diseases, and any third use of drugs will be excluded from the study. Patients will be placed in one of the following groups by random block sampling method: 600 group, 400 group, and placebo group. Pain intensity was recorded using VAS (visual analog scale) and the incidence of nausea and vomiting during recovery and 6, 24, and 72 hours after surgery.

Participants/Inclusion and exclusion criteria
The conditions for entering the study include all patients over 18 years of age who are candidates for tibial bone fracture surgery. The conditions for not entering the study include people without significant underlying disease and neuropathy, and people who do not use pain-relieving drugs and do not abuse drugs.

Intervention groups
Patients in intervention groups receive different doses of celecoxib the night before surgery and one hour before surgery. The control group receives placebo capsules at the same time.

Main outcome variables
Postoperative pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120910010800N11**
Registration date: **2023-05-06, 1402/02/16**
Registration timing: **prospective**

Last update: **2023-05-06, 1402/02/16**
Update count: **0**

Registration date
2023-05-06, 1402/02/16

Registrant information
Name
Dariush Abtahi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2263 2611
Email address
d.abtahi@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-10, 1402/02/20

Expected recruitment end date
2023-06-10, 1402/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the preventive effect of celecoxib on pain after ankle fracture surgery

Public title
Effect of celecoxib on pain after orthopedic surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Over than 18 years old Consent to the study
Exclusion criteria:
Substance abuse Uncontrolled underlying disease Underlying neuropathy
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **55**
Randomization (investigator's opinion)
Randomized
Randomization description
At the time of admission to the orthopedic department, the patients will be randomized using the permutation block method using random numbers obtained from the table of random numbers written on the card, which will be placed in sealed non-transparent envelopes, by an anesthesia technician who is in the stages. Next, there will be no interference plan, they will be placed equally in one of the following groups. Patients in the control group will receive two placebo capsules the night before surgery and one placebo capsule one hour before surgery. Group 400 patients will receive two celecoxib 200 mg capsules the night before surgery and one placebo capsule one hour before surgery. Group 600 patients will receive two 200 mg celecoxib capsules the night before the operation and another 200 mg celecoxib capsule one hour before the operation.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, 200 mg celecoxib capsules and placebo capsules will be used, in which the celecoxib content of the capsule is replaced with an approved artificial sweetener powder. These capsules will be placed inside the envelope during the preparation of the groups' envelopes and will be given to the patient by the ward nurse (the night before the operation) and the anesthesia technician (when entering the operating room), who will not be aware of the patient's next condition. The next follow-up of the patients and data recording will be done by the anesthesiologist who is not aware of the patient group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Vice-Chancellor in Research Affairs - Shahid Beheshti University of Me
Street address
Next to Ayatollah Taleghani Hospital, Yemen Street, Shahid Arabi Street, Shahid Chamran Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2023-04-30, 1402/02/10
Ethics committee reference number
IR.SBMU.RETECH.REC.1402.077

Health conditions studied

1

Description of health condition studied
Bimalleolar fracture of lower leg
ICD-10 code
S82.84
ICD-10 code description
Bimalleolar fracture of lower leg

Primary outcomes

1

Description
Postoperative pain
Timepoint
6, 24 and 72 hours after the operation
Method of measurement
Using Visual Analogue Scale

Secondary outcomes

1

Description
Postoperative nausea and vomiting

Timepoint
6, 24, and 72 hours after surgery
Method of measurement
Patient's statement

Intervention groups

1

Description
Intervention group: Patients in the 400 group will receive two celecoxib 200 mg capsules the night before surgery and one placebo capsule one hour before surgery.
Category
Treatment - Drugs

2

Description
Intervention group: Group 600 patients will receive two 200 mg celecoxib capsules the night before the operation and another 200 mg celecoxib capsule one hour before the operation.
Category
Treatment - Drugs

3

Description
Control group: Patients in the placebo group will receive two placebo capsules the night before the operation and another placebo capsule one hour before the operation.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospital Emam Hossein
Full name of responsible person
Dariush Abtahi
Street address
Shahid Madani St
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7756 7840
Email
drdariushabtahi@yahoo.com
Web page address
https://www.ehmc.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshhin Zarghi
Street address
Tehran Province, Tehran, Velenjak, 7th Floor, Bldg No.2, SBUMS, Arabi Ave
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2243 9770
Email
Intl_office@sbmu.ac.ir
Web page address
https://en.sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dariush Abtahi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Emam Hossein Hospital, Shahid Madani St
City
Tehran
Province
Tehran
Postal code
1617763141
Phone

+98 21 2263 2611

Fax

Email

d.abtahi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dariush Abtahi

Position

Assistant Professor

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Other areas of specialty/work

Anesthesiology

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Fax

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dariush Abtahi

Position

Assistant Professor

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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

No - There is not a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

One year after the publication of the article.

To whom data/document is available

All jobs

Under which criteria data/document could be used

All non-personal patient information (anonymously) can be accessed by contacting the responsible author.

From where data/document is obtainable

Email to: drdariushabtahi@yahoo.com

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

Sending email and review by the responsible author

Comments