

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effects of Preoperative Celecoxib Administration on Pain Control After Tibial Fracture Surgery

Protocol summary

Study aim

Determining the effectiveness of different doses of celecoxib as a preventive measure in pain control after tibial fracture surgery

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 450 patients. A table of random numbers was used for randomization.

Settings and conduct

After obtaining informed consent from the patients, all patients over 18 years of age who are candidates for orthopedic surgery of tibial fracture will be studied in the operating room of Imam Hossein hospital. People with uncontrolled underlying disease, patients treated with pain-relieving drugs, patients with neuropathy, history of allergic reactions to NSAIDs, suffering from mental illnesses, and any substance abuse will be excluded from the study. Patients will be assigned to one of the following groups by random block sampling method: celecoxib 100 mg group (group A), celecoxib 200 mg group (group B), celecoxib 400 mg group (group C), and placebo group (Group O). The intensity of pain is recorded using VAS (visual analog scale) and the incidence of nausea and vomiting in recovery and 6, 18, and 24 hours after surgery.

Participants/Inclusion and exclusion criteria

All patients over 18 years of age are candidates for tibial bone fracture surgery who do not have significant underlying disease and neuropathy and are not being treated with pain-relieving drugs and do not abuse drugs.

Intervention groups

Patients in intervention groups receive different doses of celecoxib one hour before surgery. At the same time, the control group receives placebo capsules.

Main outcome variables

postoperative pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120910010800N9**

Registration date: **2022-12-07, 1401/09/16**

Registration timing: **prospective**

Last update: **2022-12-07, 1401/09/16**

Update count: **0**

Registration date

2022-12-07, 1401/09/16

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

2022-12-21, 1401/09/30

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Preoperative Celecoxib Administration on Pain Control After Tibial Fracture Surgery

Public title

Effect of celecoxib on pain control after orthopedic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Consent to participate in the study Orthopedic surgery of tibial fracture with ORIF method

Exclusion criteria:

Uncontrolled underlying disease Chronic use of pain-relieving drugs Neuropathy History of allergic reactions to NSAIDs Mental illness Substance abuse Occurrence of medical problems after surgery The need for care in the intensive care unit after surgery

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: **450**

Randomization (investigator's opinion)

Randomized

Randomization description

At the time of admission in the operating room recovery, patients will be selected by 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 next stages of the non-interventional design will be equally divided into one of the following groups: celecoxib 100 mg group (A), celecoxib 200 mg group (B), celecoxib 400 mg group (C), and placebo group. (O).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, 100 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 envelopes during the preparation of the envelopes of the groups. One hour before the operation and during recovery, group A patients will receive one celecoxib capsule and three placebo capsules, group B patients will receive two celecoxib capsules and two placebo capsules, group C patients will receive four celecoxib capsules, and group O patients will receive four placebo capsules. 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

Tehran - Shahid Chamran Highway, Yemen Street - Shahid Arabi Street, next to Ayatollah Taleghani Hospital

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-09-11, 1401/06/20

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.413

Health conditions studied

1

Description of health condition studied

Comminuted fracture of shaft of tibia

ICD-10 code

S82.25

ICD-10 code description

Comminuted fracture of shaft of tibia

Primary outcomes

1

Description

postoperative pain

Timepoint

Recovery time, 6, 18, and 24 hours after surgery

Method of measurement

Using Visual Analogue Scale

Secondary outcomes

1

Description

Postoperative nausea and vomiting

Timepoint

Recovery time, 6, 18, and 24 hours after surgery

Method of measurement

Patient's statement

Intervention groups

1

Description

Intervention group: Group A patients receive one celecoxib capsule and three placebo capsules one hour before surgery.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group: Group B patients receive two celecoxib capsules and two placebo capsules.

Category

Treatment - Drugs

3

Description

Intervention group: Group C patients receive four celecoxib capsules.

Category

Treatment - Drugs

4

Description

Control group: Control group: Group O patients receive four placebo capsules.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Emam Hossein

Full name of responsible person

Dariush Abtahi

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Shahid Madani St

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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

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Intl_office@sbmu.ac.ir

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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

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

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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

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

No - There is not a plan to make this available

Analytic Code

No - There is not 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

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