

# 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

**Street address**

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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**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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Emam Hossein Hospital, Shahid Madani St

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
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## Person responsible for updating data

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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