Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

A Comparison of the preventive effect of 100 mg and 200 mg oral celecoxib on shivering during and after orthopedic lower extremity surgery under the spinal anesthesia in patients and the control group

Protocol summary

Study aim

This study aimed to compare the anti-shivering effects of 100 mg and 200 mg of this drug in the control group undergoing orthopedic lower extremity surgeries under spinal anesthesia and the patients with American Society of Anesthesiologists (ASA) 1.

Design

Two arm parallel group randomized trial with blinded postoperative care and outcome assessment

Settings and conduct

In this simple randomized double blind clinical trial that was conducted at Ayatollah Kashani Hospital in Isfahan on control group, patients undergoing elective orthopedic surgery of the lower extremity under spinal anesthesia as well as patients with ASA1 were evaluated. The first group of patients received Celecoxib 100mg three hours before SA. The second group received Celecoxib 200mg three hours before SA, and the third group received placebo three hours before SA. The incidence and severity of shivering is measured 10 minutes after SA, and subsequently at 15 minutes intervals till the end of surgery in all three groups. The medications were coded to prevent any bias. The coded medications were given by the first Anesthesiologist, and the data were recorded by the second Anesthesiologist.

Participants/Inclusion and exclusion criteria

Participants: the patients undergoing elective orthopedic surgery of the lower extremity under spinal anesthesia Entry condition: patients with ASA1, age between 18 and 65 No-entry conditions: history of hypertension; cardiovascular disease; allergy to Coxib drugs; ...

Intervention groups

first group is received Celecoxib 100 mg, second group Celecoxib 200 mg and third group is received placebo

Main outcome variables

Incidence and severity of shivering during the operation and the recovery period based on Tsai and Cha scale

General information

Reason for update

Acronym

spinal

IRCT registration information

IRCT registration number: **IRCT20101211005362N23**
Registration date: **2020-03-25, 1399/01/06**
Registration timing: **retrospective**

Last update: **2020-03-25, 1399/01/06**
Update count: **0**

Registration date

2020-03-25, 1399/01/06

Registrant information

Name

Mohammadreza Safavi

Name of organization / entity

Anesthesiology and Critical Care Research Center, Isfahan University of Medical Sciences, Isfahan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-05-21, 1396/02/31

Actual recruitment start date

2016-05-21, 1395/03/01

Actual recruitment end date

2017-05-21, 1396/02/31

Trial completion date

2017-05-21, 1396/02/31

Scientific title

A Comparison of the preventive effect of 100 mg and 200 mg oral celecoxib on shivering during and after orthopedic lower extremity surgery under the spinal anesthesia in patients and the control group

Public title

oral celecoxib on shivering during and after orthopedic lower extremity surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

the patients with American Society of Anesthesiologists (ASA) 1 age between 18 and 65

Exclusion criteria:

History of hypertension Sever cardiovascular disease Allergy to Coxib drugs Psychological disorder based on history Temperature less than 36 or more than 38 Celsius degree Usage of alcohol and opioids Usage of vasodilators Allergy to Aspirin

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **105**

Actual sample size reached: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Random Allocation. Numbered balls from 1 to 105 were put in a box. Then were pulled out randomly and the number was written in a group of Celecoxib 100 mg, Celecoxib 200 mg and placebo, respectively. Each number represented the order of patients entry to the hospital and had the entrance requirements and had given the consent for entering to the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Gبا ماركائين 5/0% با سوزن L3-L422 بي حسي نخاعي در فضاي Quincke spinal با كد خاص 3 celecoxib انجام گرفت.كپسول‌هاي به بيمار داده شد. اين كار توسط متخصص بيهوشي SA ساعت قبل از اول انجام و داده‌ها توسط متخصص بيهوشي دوم از طريق پرسشنامه جمع‌آوري و بدين طريق كورسازي صورت مي‌گرفت

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan university of medical science, Isfahan, Iran

City

isfahan

Province

Isfehan

Postal code

81857647852

Approval date

2017-05-21, 1396/02/31

Ethics committee reference number

IR.MUI.MED.REC.1396.260

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

T88.51

ICD-10 code description

Hypothermia following anesthesia

Primary outcomes

1

Description

Incidence and severity of shivering based on Tsai and Cha scale

Timepoint

every 15 minutes

Method of measurement

objective

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: received Celecoxib 100mg three hours before operation.

Category

Treatment - Drugs

2

Description
Second intervention group: received Celecoxib 200mg three hours before operation.
Category
Treatment - Drugs

3

Description
Control group: received placebo three hours before operation.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani hospital
Full name of responsible person
Seyed Mohamadreza Safavi
Street address
Alzahra hospital, Sofeh Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Seyed Mohamadreza Safavi
Position
Professor
Latest degree
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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
Undecided - It is not yet known if there will be 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