

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of the prophylactic effects of gabapentin, pregabalin and oral celecoxib and placebo on controlling of postoperative pain in orthopaedic lower extremities surgery with spinal anesthesia

Protocol summary

Study aim

Comparison of the prophylactic effect of gabapentin, pregabalin and oral celecoxib on controlling of post operative pain in orthopaedic surgery of the lower extremities.

Design

A clinical trial with a community- based and pragmatic control group with parallel-groups double blind randomised

Settings and conduct

One hundred and twenty patients undergoing lower limb orthopedic surgery in Al-Zahra hospital of Isfahan were selected. To make a double- blinded study the patients were unaware of their groups and the physician who has no role in the process of data collection put every drug in the same capsules with different codes. The physician who prescribed the drugs was unaware of drug content of each capsule as well one hour before the act of spinal anesthesia, the drugs were taken and right after the surgery, pain was measured using the visual analog scale(VAS).

Participants/Inclusion and exclusion criteria

Inclusion criteria were candidates for elective lower limb orthopedic surgery, absence of uncontrolled systemic diseases. Exclusion criteria include patient's dissatisfaction, failing of spinal anesthesia (it was tried no more than twice maximum)

Intervention groups

An hour prior to spinal anesthesia each group was assigned one of the following three medications. 300mg of Gabapentin was given to the first group, 75mg of Pregabalin to the second group and 200mg of Celecoxib to the third group. Placebo was assigned to the 4th group.

Main outcome variables

Post orthopedic surgical pain of the lower extremities

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180722040557N1**

Registration date: **2018-08-07, 1397/05/16**

Registration timing: **prospective**

Last update: **2019-01-28, 1397/11/08**

Update count: **1**

Registration date

2018-08-07, 1397/05/16

Registrant information

Name

Marzie Taghvaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5321 5240

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dr.taghvaie@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-11, 1397/05/20

Expected recruitment end date

2018-10-02, 1397/07/10

Actual recruitment start date

2018-08-15, 1397/05/24

Actual recruitment end date

2018-10-09, 1397/07/17

Trial completion date

2018-10-09, 1397/07/17

Scientific title

Comparison of the prophylactic effects of gabapentin, pregabalin and oral celecoxib and placebo on controlling of postoperative pain in orthopaedic lower extremities surgery with spinal anesthesia

Public title

Effect of gabapentin, pregabalin and oral celecoxib on controlling of postoperative pain in orthopaedic lower extremities surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Candidacy of elective lower limb orthopaedic surgery No contraindication for spinal anesthesia No restriction for sitting position Patient's tendency to spinal anesthesia No risk of increasing intra cranial pressure No suffering from uncontrolled diseases No coagulation disorders

Exclusion criteria:

Patient's dissatisfaction to keep on cooperation Failing of spinal anesthesia (it was tried twice maximally)

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients were randomly assigned into four groups of 30, the first, second, third and fourth patients were divided into four groups, and the subsequent patients were randomly distributed in groups so that the sample size Enough in all four groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the current double-blinded study, the patients were unaware of their groups and the physician who did not participate in the process of data collection put all the drugs in the same capsules with different codes. The physician who prescribed the drugs was unaware of drug content of each capsule as well.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Science

Street address

Hezar Jerib Avenue, Isfahan , Iran

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Province

Isfahan

Postal code

8174673461

Approval date

2017-05-31, 1396/03/10

Ethics committee reference number

396335

Health conditions studied

1

Description of health condition studied

Postoperative pain of lower limb following orthopaedic lower limb surgery

ICD-10 code

M79.6

ICD-10 code description

Pain in limb, hand, foot, fingers and toes

Primary outcomes

1

Description

Post orthopedic surgical pain of the lower extremities

Timepoint

Each 60 minutes for 2 times and each 6 hours for the next 4 times

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One hour prior to spinal anesthesia group 1 received 300 mg gabapentin,

Category

Treatment - Drugs

2

Description

Intervention group: One hour prior to spinal anesthesia group 2 received 75 mg pregabalin

Category

Treatment - Drugs

3

Description

Intervention group: One hour prior to spinal anesthesia group 3 received 200 mg celecoxib

Category

Treatment - Drugs

4

Description

Control group: One hour prior to spinal anesthesia control group received placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dorna Kheirabadi

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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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Web page address

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

Marzie Taghvaie

Position

Asistant

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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

Yes - There is a plan to make this available

Analytic Code

Not applicable

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

publication of the results

When the data will become available and for how long

Accesibility after data analysis

To whom data/document is available

all researchers in different fields

Under which criteria data/document could be used

They should cite to the paper

From where data/document is obtainable

email to correspond author

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

He/She should explain about their research clearly and get the permission of all authors. Then He/She can use the data with citation to our paper

Comments