Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 oprative pain in orthopeadic surgry 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

Email address

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 postoprative pain in orthopaedic lower extremities surgrey

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 coopration Failling 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

City
Isfahan

Province
Isfehan

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 sergical 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 recieved placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Dorna Kheirabadi
Street address
N0.10 , Almasian Alley, 7th Alley , East Nazar street
City
Isfahan
Province
Isfehan
Postal code
8173663364
Phone
+98 31 3624 7909
Email
dr.dorna.kheirabadii@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjooy Javanmard
Street address
Isfahan university of medical science ,Hezar Jerib Avenue,
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 8138
Fax
Email
haghjoo@bmn.ac.ir
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
Street address
No 17, 6 Ave, Esteghlal Blvd, Shahreza Town
City
Shahreza
Province
Isfehan
Postal code
8618676781
Phone
+98 31 5321 5240
Fax
Email
dr.taghvaie@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohamdreza Safavi
Position

Professor of anesthesiology

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Alzahra Hospital ,Shohadaye Soffe Blvd, Isfahan City

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
safavi@med.mui.ac.ir

Person responsible for updating data

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

Street address
No 17, 6 Ave, Esteghlal Blvd, Shahreza Town

City
Shahreza

Province
Isfehan

Postal code
8618676781

Phone
+98 31 5321 5240

Fax

Email
dr.taghvaie@gmail.com

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