

# 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

##### 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 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

##### City

Isfahan

##### 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

#### Street address

N0.10 , Almasian Alley, 7th Alley , East Nazar street

#### City

Isfahan

#### Province

Isfahan

#### 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

Isfahan

#### Postal code

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#### 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

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#### Province

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#### 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**

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Isfahan

**Postal code**

8174675731

**Phone**

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**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**

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**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**