

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Effect of a single dose of Pregabalin on intraoperative hemodynamic changes and duration of analgesia in spinal anesthesia for tibial bone fracture orthopedic surgery

Protocol summary

Summary

Effect of a single dose of Pregabalin on intraoperative hemodynamic changes and duration of analgesia in spinal anesthesia for tibial bone fracture orthopedic surgery. This study was a randomized clinical trial with two groups Pregabalin (capsules 150 mg) and placebo (drug capsules in appearance, but no active ingredient) to control the dependent variable is the before and after of the intervention. Non-emergency patients in ASA class 1, age 20 to 70 years with tibia fractures in the study of patients with diseases or conditions affecting the hemodynamic status and pain leaving 120 eligible patients hospitalized part Orthopaedic Hospital Khatma Lanbya, in 1393 who is scheduled to undergo surgery Orthopaedic Fracture Tibia spinal anesthesia is reflected by the sampling block with random allocation of both the experimental group and the placebo group with written informed consent to enter the study were check favors, hour before spinal anesthesia, two capsules 75 mg Pregabalin Fizer manufacturing plant in America or two placebo group consumed that her presence helped the researcher. The mean arterial pressure, pulse, length and number of analgesia after spinal anesthesia is checked. It is assumed that this drug causes hemodynamic stability during long will the pain of spinal anesthesia

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121020272N1**

Registration date: **2015-08-24, 1394/06/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-24, 1394/06/02

Registrant information

Name

Amir Moosavi

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5717

Email address

amir.moosavi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of a single dose of Pregabalin on intraoperative hemodynamic changes and duration of analgesia in spinal anesthesia for tibial bone fracture orthopedic surgery

Public title

Effect of pregabalin on hemodynamic on pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The non-emergency patients ASA class 1; Age 20 to 70 years; candidates for orthopedic surgery tibia fracture; the prior written consent from patient; social class and level of consciousness that patient is able to cooperate ; Exclusion criteria were the beginning of the study: hemodynamic status is affected with diseases or conditions such as heart disease, diabetes, renal ;The history of allergy to gabapentin or Pregabalin, drug use, regular use of alcohol or smoking more than 5 years, the diseases of the brain and nerves ; spinal anesthesia during surgery after more than ninety minutes ; patients who require drugs that affect hemodynamic ; pregnancy ; refusal of doing research and refusal of spinal anesthesia patients ; patients with coagulopathy ; infection in site of the spinal anesthesia ; any interference with the absorption of oral drugs that can cause digestive disorders ; The disease affects the feeling of pain, such as diabetes, drug addiction ; Monitor the patient is indicative of Abnormal pulse , mean arterial pressure ; The need for analgesics for pain relief
Exclusion criteria during the study: Abnormal bleeding during surgery ; Intraoperative cardiovascular and brain complications ; Monitor the patient is indicative of abnormal pulse, mean arterial pressure.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University of Medical Sciences

Street address

Doctor Hesab square

City

Zahedan

Postal code

9816743463

Approval date

2014-09-28, 1393/07/06

Ethics committee reference number

6907

Health conditions studied

1

Description of health condition studied

Spinal anesthesia

ICD-10 code

T88.7

ICD-10 code description

Unspecified adverse effect of drug or medicament

Primary outcomes

1

Description

mean arterial pressure: pulse

Timepoint

Thirty minutes before feeding capsules every ten minutes. Every ten minutes after spinal anesthesia to complete the surgery

Method of measurement

Monitoring of vital signs

2

Description

duration of analgesia in spinal anesthesia

Timepoint

After the onset of analgesia by spinal anesthesia Until the onset of pain

Method of measurement

Timer(minute)

Secondary outcomes

1

Description

No exist

Timepoint

No exist

Method of measurement

No exist

Intervention groups

1

Description

pregabalin group (150 mg capsule): because of 150 mg capsules it's not available on the market of Iran that is given two 75 mg capsules instead. A hour before spinal

anesthesia is used by nurses in the orthopedic unite, who was not aware of drugs the patient is given effect by comparison with the placebo group on the dependent variables arterial medium voltage, pulse duration of analgesia after spinal anesthesia are considered.

Category

Other

2**Description**

placebo group (Appearance, but no active ingredient drug capsules). A hour before spinal anesthesia is used by nurses in the orthopedic unite, who was not aware of drugs the patient is given effect by comparison with the placebo group on the dependent variables arterial medium voltage, pulse duration of analgesia after spinal anesthesia are considered.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Khatam Orthopedic Section Hospital

Full name of responsible person

Doctor Alireza Rahat Dahmardeh

Street address

Khatam Hospital, Jame Jam Boulevard

City

Zahedan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Deputy for research Zahedan University of Medical Sciences

Full name of responsible person

DR Hooshang Rafigh Doost

Street address

Doctor Hesabi Square

City

Zahedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Deputy for research Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Amir Moosavi

Position

Anesthesiology Assistant

Other areas of specialty/work**Street address**

Khatam Hospital, Jame Jam Boulevard

City

Zahedan

Postal code

9815733169

Phone

+98 54 3322 0501

Fax

+98 54 3322 0504

Email

amir.moosavi@zaums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zahedan Medical Science Univesity

Full name of responsible person

Alireza Rahat Dahmardeh

Position

Anesthesiologist

Other areas of specialty/work**Street address**

Khatam Hospital, Jame Jam Boulevard

City

Zahedan

Postal code

9815733169

Phone

+98 915 542 0911

Fax

+98 543322504

Email

Dr.dahmardeh@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Amir Moosavi

Position

Anesthesiology Assistant

Other areas of specialty/work

Street address

Khatam Hospital, Jame Jam Boulevard

City

Zahedan

Postal code

009815733169

Phone

+98 543220501

Fax

+98 543220504

Email

amir.moosavi@zaums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty