

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effect of a single dose of oral Pregabalin with single oral dose of gabapentin on acute pain management after tibia fixation surgery

Protocol summary

Summary

The purpose of this study is to provide the best post operative analgesia. Sixty patients aged 17 to 65 years with tibial fracture underwent tibial fixation orthopedic surgery and spinal anesthesia and had no mental disorder, hepatic or renal failure and addiction. Patients with random block classification were divided in to 2 groups. Gabapentin (G) group and pregabalin(P) group. Patient receive in the(G) group 300 mg oral Gabapentin, 2 hours before operation and in the (P) group, 150 mg, oral pregabalin 1 hour before operation. paine by VAS, nausea, vomiting and vertigo before exit from recovery room, 6 and 12 hours after surgery were monitored and documented. If VAS>3, intravenous morphine(0.1mg) will be infused.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502126186N8**

Registration date: **2015-03-10, 1393/12/19**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-03-10, 1393/12/19

Registrant information

Name

Bahram Naderi Nabi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2015-03-25, 1394/01/05

Expected recruitment end date

2015-09-27, 1394/07/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of a single dose of oral Pregabalin with single oral dose of gabapentin on acute pain management after tibia fixation surgery

Public title

The effect of a single dose of oral Pregabalin single oral dose of gabapentin on pain control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 17 to 65 years old; ASA I, II; being candidate for tibial fixation orthopedic surgery and spinal anesthesia. Exclusion criterion: patient dissatisfaction for spinal anesthesia.

Age

From **17 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Guilan University of Medical Sciences

Street address

Shahid Beheshti Freeway

City

Rasht

Postal code

4193713194

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

19304742021

Health conditions studied**1****Description of health condition studied**

Pain

ICD-10 code

M89.8

ICD-10 code description

Other specified disorders of bone

Primary outcomes**1****Description**

Pain

Timepoint

Before spinal anesthesia, before exit from recovery room, 6 and 12 hours after surgery

Method of measurement

Visual Analog Scale

Secondary outcomes

empty

Intervention groups**1****Description**

First group: patients receive 150 mg, oral pregabalin 1 hour before operation. Post operation, VAS, nausea, vomiting and vertigo before exit from recovery room, 6 and 12 hours after surgery were monitored and documented. If VAS>3, intravenous morphine (0.1mg) will be infused.

Category

Treatment - Drugs

2**Description**

In the Second group: patients receive 300 mg oral Gabapentin, 2 hours before operation. Post operation, VAS, nausea, vomiting and vertigo before exit from recovery room, 6 and 12 hours after surgery were monitored and documented. If VAS>3, intravenous morphine (0.1mg) will be infuse.

Category

Treatment - Drugs

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

Poursina Hospital

Full name of responsible person

Bahram Naderi Nabi

Street address

Porsina Hospital

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

Vice chancellor for research of Guilan University of Medical Sciences

Full name of responsible person

Abtin Heidarzadeh

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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
Vice chancellor for research of Guilan 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
empty

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Guilan University of Medical Sciences

Full name of responsible person
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Position
Anesthesiologist

Other areas of specialty/work

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Medical laboratory Sciences Technician/ Bachelor's Degree

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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