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)
Phone
+98 13 3323 4600
Email address
naderi_bahram@gums.ac.ir

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 between17 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
City
Rasht

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
Street address
Shahid Beheshti Freeway
City
Rasht
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
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
Bahram Naderi Nabi
Position
Anesthesiologist
Other areas of specialty/work
Street address
Poursina
City
Rasht
Postal code
4139638459
Phone
+98 13 3366 3070
Fax
+98 13 3334 5132
Email
naderi_bahram@yahoo.com
Web page address
www.arc.gums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Guilan University of Medical Science
Full name of responsible person
Bahram Naderi Nabi
Position
Anesthesiologist
Other areas of specialty/work
Street address
Poursina Hospital
City
Rasht
Postal code
4193955599
Phone
+98 13 3366 3070
Fax
+98 13 3334 5132
Email
arcguilan1392@gmail.com
Web page address
www.arc.gums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Hedyeh Nemati
Position
Medical laboratory Sciences Technician/ Bachelor's Degree
Other areas of specialty/work
Street address
Poursina Hospital
City
Rasht
Postal code
4193713194
Phone
+98 13 3366 3070
Fax
+98 13 3334 5132
Email
arcguilan1392@gmail.com
Web page address
www.arc.gums.ac.ir

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