

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of adding oral gabapentin to morphine patient-controlled iv analgesia (PCIA) on pain after orthopedic surgery

Protocol summary

Summary

In this study, after obtaining the approval of the institutional board committee (Iran University of Medical Sciences, IUMS) and written consent of the patients, 76 patients aged 20-70 years old, classified ASA physical status I-II who were candidate for orthopedic surgery on lower extremity fractures under similar general anesthesia were studied. Patients were randomly divided in two groups (control and case). For postoperative analgesia in both groups patient controlled intravenous analgesia (PCIA) with morphine (0.2mg/ml) was given on a continuous flow rate (5ml/h). In the case of breakthrough pain (VAS>3), 2mg iv morphine was administered. In the case group, loading dose of 600mg oral gabapentin within 6 hours after surgery and 300mg every 12 hours was administered until 72 hours after surgery. In the control group placebo was given instead of gabapentin. Pain score were evaluated by a visual analog scale (VAS). In cases of the VAS<2, the continuous infusion of morphine were decreased to %50. Pain score, analgesic consumption and side effects were assessed every 12 hours for three days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010072366N3**

Registration date: **2010-10-23, 1389/08/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-10-23, 1389/08/01

Registrant information

Name

Farnad Imani

Name of organization / entity

Iran University of Medical Sciences (IUMS)

Country

Iran (Islamic Republic of)

Phone

+98 21 6651 5758

Email address

imani.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences (IUMS)

Expected recruitment start date

2009-01-19, 1387/10/30

Expected recruitment end date

2010-01-20, 1388/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding oral gabapentin to morphine patient-controlled iv analgesia (PCIA) on pain after orthopedic surgery

Public title

The effect of adding oral gabapentin to morphine patient-controlled iv analgesia (PCIA) on pain after orthopedic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients aged 20-70 years old, classified ASA physical status I-II who were candidate for orthopedic surgery on lower extremity fractures under general anesthesia. Exclusion criteria: severe

uncontrolled co-existing diseases (CNS, convulsive, cardiovascular, ...), renal failure, concurrent use of anticonvulsant drug and /or other analgesic drugs, alcohol, addiction, known allergy to gabapentin or morphine, and patient refusal.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **76**

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

Iran University of Medical Sciences

Street address

Crossroads of Hemmat & Chamran Expressways

City

Tehran

Postal code

14496

Approval date

2009-03-06, 1387/12/16

Ethics committee reference number

1177710

Health conditions studied

1

Description of health condition studied

Analgesia after orthopedic surgery for lower extremity fractures

ICD-10 code

S72

ICD-10 code description

Fracture of femur

Primary outcomes

1

Description

postoperative analgesia

Timepoint

every 12 hrs

Method of measurement

Visual analogue scale, and analgesic consumption

Secondary outcomes

1

Description

Side effects

Timepoint

every 12 hours

Method of measurement

Observation and evaluation of patients

Intervention groups

1

Description

Control group: administration of placebo every 12 hours in patient under iv morphine pump for three days.

Category

Placebo

2

Description

Case group: administration of gabapentin 300 mg every 12 hours in patient under iv morphine pump for three days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool-Akram Hospital

Full name of responsible person

Farnad Imani

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences (IUMS)

Full name of responsible person
Dr Maziar Moradi-lakeh, Director of Research and Technology

Street address
Crossroads of Hemmat & Chamran Expressways

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran University of Medical Sciences (IUMS)

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
Iran University of Medical Sciences

Full name of responsible person
Farnad Imani

Position
Chairman, Department of Anesthesiology

Other areas of specialty/work

Street address
Department of Anesthesiology & Pain Medicine,
Rasool-Akram Hospital

City
Tehran

Postal code
1445613131

Phone
+98 21 6651 5758

Fax
+98 21 6651 5758

Email
farimani@iums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person

Farnad Imani

Position
Associate professor

Other areas of specialty/work

Street address
Rasool-Akram Hospital

City
Tehran

Postal code
1445613131

Phone
+98 21 6651 5758

Fax
+98 21 6651 5758

Email
farimani@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Farnad Imani

Position
Chairman/ Department of Anesthesiology

Other areas of specialty/work

Street address
Department of Anesthesiology & Pain Medicine,
Rasool-Akram Hospital, Niayesh St, Sattar-khan Av

City
Tehran

Postal code
1445613131

Phone
+98 21 6651 5758

Fax
+98 21 6651 5758

Email
farimani@iums.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