

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of preoperative oral gabapentin on post operative pain in opioid addicted patients

Protocol summary

Summary

Objectives: To investigate the effects of gabapentin in postoperative pain after orthopedic surgery in patients addicted to opioids. Research Design: A randomized, double-blind, clinical trial. Inclusion criteria: age 70-20 years, ASA class I- II, patients undergoing surgery for hip fracture and lower extremity. Exclusion criteria: hypersensitivity to the Gabapentin, a seizure history, a history of taking gabapentin, mental illness, liver or kidney disease, pregnancy, multiple simultaneous fractures. 64 Patients are randomly divided into two groups P and G. Patients in recovery room were treated according to the severity of pain as follows: morphine 2 mg every 5 minutes with pain score more than 7 until the pain score reaches to the 4, and 1 mg morphine every 5 minutes with pain score of 4 -6 until the pain intensity reaches to 4. In the surgery ward morphine pump was used for patients in the both groups, as follows, a solution of 0.5 mg per/cc with 2 mg and interval locked out 6 minutes and the maximum dose of 50 mg every 4 hours. At 2, 4, 6, 12, 18 and 24 hours after surgery parameters (in the time of the rest), insomnia, shivering, nausea, urinary retention, sedation and degree of patient satisfaction measured and data were recorded in a special form.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014122019470N4**

Registration date: **2015-04-01, 1394/01/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-04-01, 1394/01/12

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Science

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of preoperative oral gabapentin on post operative pain in opioid addicted patients

Public title

Effect of preoperative oral gabapentin on post operative pain in opioid addicted patients with lower extremity orthopedic surgeries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age 70-20 years, ASA class I- II, patients undergoing surgery for hip fracture and lower extremity. Exclusion criteria: hypersensitivity to the

Gabapentin, a seizure history, a history of taking gabapentin, mental illness, liver or kidney disease, pregnancy, multiple simultaneous fractures

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 64

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

Ethics Committee of Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

CP-P-9356-5676

Health conditions studied

1

Description of health condition studied

Major Orthopedic Surgery

ICD-10 code

M96.6

ICD-10 code description

Fracture of Bone following Insertion of Orthopedic Implant, joint,...

Primary outcomes

1

Description

the effect of oral gabapentin on post operative pain in opioid addicted patients with orthopedic surgeries

Timepoint

pain score were recorded at 0,1,3,6 and 24 hours in the post-operative period.

Method of measurement

NRS

Secondary outcomes

1

Description

Patient's satisfaction

Timepoint

at 0,1,3,6 and 24 hours in the post-operative period.

Method of measurement

Four Point Categorical Scale

Intervention groups

1

Description

Intervention group: patients received 300 mg gabapentin one hour before the surgery.

Category

Treatment - Drugs

2

Description

control group: patients received same capsule as placebo one hour before the surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Hospital

Full name of responsible person

Street address

Chamran Hospital, Chamran Boulevard

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

Street address

Vice Chancellor for Research, Shiraz University of Medical Sciences, 7th floor, Central Building of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

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, Shiraz 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

Shiraz University Of Medical Science

Full name of responsible person

Elham Sabokseir

Position

Physician, Anesthesiology Resident

Other areas of specialty/work

Street address

Anesthesiology Department, Shahid Faghihi Hospital, Zand street

City

Shiraz

Postal code

Phone

+98 71 3235 7282

Fax

Email

sabokseir@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University Of Medical Sciences

Full name of responsible person

Saeid Khademi

Position

Anesthesiologist

Other areas of specialty/work

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Postal code

Phone

+98 71 3235 7282

Fax

Email

khademisaeid@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

English Consultant, Anesthesiology Research Center Staff

Other areas of specialty/work

Street address

Anesthesiology Office, Namazi Hospital

City

Shiraz

Postal code

Phone

+98 71364774270

Fax

Email

masihif@sums.ac.com; masihifarzane@yahoo.com

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