Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Comparison between the effect of preemptive Gabapentin and Fascia Iliaca block in reduction of postoperative pain of femoral shaft surgery

Protocol summary

Summary

All patient who accept to participate in the study divided to two equals group randomly(n=30). In case group all patient recieve facia illica block with 20 CC bupivacainene 0.5%(100 mg.fascia iliaca block is an injection under the inguinal region (femoral or fascia iliaca block); while doing, fascia iliaca block anaesthetic solution is distributed to the femoral nerve, lateral femoral cutaneous nerve and occasionally to the genito-femoral nerve and this made patient painless for a long time. In control group all patient recieve 600 mg of gabapentin 2 hours before surgery. Post operative pain score,first demand of analgesic and total amount of analgesic in first 24 hours will be noted and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203021936N9**
Registration date: **2012-06-07, 1391/03/18**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-06-07, 1391/03/18

Registrant information

Name

Abdolreza Najafi Anaraki

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Bushehr University of Medical Sciences

Expected recruitment start date

2012-07-01, 1391/04/11

Expected recruitment end date

2012-11-01, 1391/08/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison between the effect of preemptive Gabapentin and Fascia Iliaca block in reduction of postoperative pain of femoral shaft surgery

Public title

The Comparison between the effect of preemptive Gabapentin and Fascia Iliaca block in reduction of postoperative pain of femoral shaft surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criterion: all patients with femoral shaft fracture between 18 till 45 years old who sign consent form.
Exclusin criteria: sensitivity to gabapentin; local anesthetic; history of opioid abuser; peripheral neuropathy; asthma; diabetes mellitus and use of analgesic 8 hours before surgery.

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Bushehr university of medical college

Street address

Bushehr -siraf avenue

City

Bushehr

Postal code

Approval date

2012-05-06, 1391/02/17

Ethics committee reference number

B-91-14-1

Health conditions studied

1

Description of health condition studied

Post operative pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Post operative pain

Timepoint

24 hours

Method of measurement

Visual pain score

Secondary outcomes

1

Description

First demand for analgesic

Timepoint

First 24 hours

Method of measurement

Patients medical records

Intervention groups

1

Description

In control group all the patients recieve 600 mg Gabapentin orally 2 hours before surgery. Gabapentin is a gaba amino buteric acid inhibitor and can prevent post operative pain

Category

Treatment - Drugs

2

Description

In experimental group all the patient recieve facia illica block just before surgey with 20 mililiter bupivacaine .05% fascia iliaca block is an injection under the inguinal region (femoral or fascia iliaca block), When you do fascia iliaca block anaesthetic solution is distributed to the femoral nerve, lateral femoral cutaneous nerve and occasionally to the genito-femoral nerve and this made patient painless for a long time

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Zahar hospital

Full name of responsible person

Street address

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bushehr University of Medical Sciences

Full name of responsible person

Dr Majid Asady

Street address

Bushehr university of medical science-dr najafianaraki

City

Bushehr

Grant name

Grant code / Reference number

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