

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of preemptive analgesia with (Gabapentine, Celecoxib, Acetaminophen) on pain and anxiety score after femoral fractures surgery

Protocol summary

Summary

(1) Objectives: evaluate the effect of three pre- drug combinations of gabapentin , celecoxib , and acetaminophen in reducing anxiety, pain , need for postoperative morphine consumption and side effects in adult patients were Distal femoral fracture surgery plating. (2) Design: Randomized controlled trial. (3) Setting and conduct: Sample size of 100 patients will randomly assign into intervention (preemptive analgesia) or control (placebo) group and will be treated in academic orthopedic hospital. (4) Inclusion criteria: age between 25 to 45 years, ASA versus I and II. Exclusion criteria: failure of spinal anesthesia or if take more than 90 minutes. (5) Interventions: one hour before surgery, under the direct supervision of a nurse who was unaware of the status of drug or placebo to patients three oral gabapentin (600 mg dose), celecoxib (200 mg dose) and acetaminophen (500 mg dose) plus 50cc water is fed to the case group and control group given a placebo. (6) Main outcome measures: Primary outcome is VAS score of pain which will be assessed at 1, 2, 3, 4, 8 and 12 hour after surgery, the first analgesic request after resolution of spinal anesthesia, opioid consumption and respiratory rate, pulse oximetry, heart rate, blood pressure and other side effects mentioned temporal resolution within 24 hours checked, STAI anxiety criteria.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051417681N1**

Registration date: **2014-05-30, 1393/03/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-30, 1393/03/09

Registrant information

Name

Mehran Soleymanha

Name of organization / entity

Guilan University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Guilan university of medical science

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of preemptive analgesia with (Gabapentine, Celecoxib, Acetaminophen) on pain and anxiety score after femoral fractures surgery

Public title

The effect of preemptive analgesia on pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients candidates for surgery under spinal anesthesia plating of distal femur; aged between 25 to 45 years; patient satisfaction; ASA (American Society of Anesthesiologists class I and II) Exclusion criteria: presence of underlying conditions (such as diabetes) or organ failure; history of drug or alcohol addiction; history of cardiovascular problems or heart stroke; history of allergy to opioids and gabapentin and celecoxib; renal dysfunction; multiple trauma; obesity (BMI greater than 35); pathologic fractures; and people that receive housing long time for any reason.

Age

From **25 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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, Guilan University of Medical Sciences

Street address

Research vice-chancellor of Guilan university of medical sciences building, Shahid Beheshti blv.

City

Rasht

Postal code

Approval date

2014-03-10, 1392/12/19

Ethics committee reference number

1920452606

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

F41.0

ICD-10 code description

Panic disorder [episodic paroxysmal anxiety]

2

Description of health condition studied

pain

ICD-10 code

Z09.4

ICD-10 code description

Follow-up examination after treatment of fracture

Primary outcomes

1

Description

pain

Timepoint

1,2,3,4,8,12 heures after surgery

Method of measurement

vas score

2

Description

anxiety

Timepoint

1,2,3,4,8,12 heures after surgery

Method of measurement

STAI

Secondary outcomes

empty

Intervention groups

1

Description

One hour before surgery, are given a placebo to control group patients.

Category

Placebo

2

Description

one hour before surgery , three-dose oral gabapentin 600 mg, celecoxib 200 mg and 500 mg of acetaminophen with 50 cc of water is fed to case group patients

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Hospital

Full name of responsible person

Mehran Soleymanha

Street address

Parastar Street

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Guilan University of Medical Sciences

Full name of responsible person

Dr. Abdolrasoul Sobhani, Research chancellor of Guilan university of medical science

Street address

Research vice-chancellor of Guilan university of medical sciences building, Shahid Beheshti blv.

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, 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 Science

Full name of responsible person

Dr Mehran Soleymanha

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Assistant Professor

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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