Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comoarison of post operative analgesia in patients under tibia fracture surgeries with Celecoxib adminitrasion in different preoperative times

Protocol summary

Summary

The main goal was comparison of postoperative pain in leg fracture patients with preoperative administration of different doses of CELECOXIB. This randomized double blinded study was done on ASA I , II patients in 20 -40 candidated for leg fracture operation.inclusion criteria were: no history of opium addiction, no history of cardiac disease and previous cardiac problems (MI , CAD), no history of CVA, no previous analgesic consumption, exclusion criteria were : analgesic consumption prior premedication, time of surgery more than 3 h , multiple trauma and height less than 150cm. smaple size was 60 (20 in each group). they divided in 3 groups : in group 1 400 mg celecoxib administered the night before surgery.in group 2 , 200 mg the night before and 200 mg in the morning , and group 3 recieved no premedication. After intravenous infusion of 5ml/kg normal saline to all patients, spinal anesthesia done with 3 ml bupivacaine 0.5% .The time of starting and ending of the operation and anesthesia was recorded. level of anesthesia under T10 mentioned as the ending time of anesthesia and in cases with level T10 at the beginning of the operation, leve L1 considered as the end time of anesthesia. Mean of VAS and the time of first analgesic request by the patients and total opium consumption during 24h after surgery was compared between 3 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010194969N1**
Registration date: **2011-09-10, 1390/06/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-09-10, 1390/06/19

Registrant information

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Recruitment status

Recruitment complete

Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2009-03-21, 1388/01/01

Expected recruitment end date
2009-09-23, 1388/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comoarison of post operative analgesia in patients under tibia fracture surgeries with Celecoxib adminitrasion in different preoperative times

Public title

Effects of different doses of celecoxib on pain control after leg fracture surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 20-40 y ASA I , II patients candidated

for leg fracture operation, without history of opium addiction, no history of cardiac disease and previous cardiac problems (MI , CAD), no history of CVA, no previous analgesic consumption, Exclusion criteria : analgesic consumption prior premedication, time of surgery more than 3 h , multiple trauma

Age
From **20 years** old to **40 years** old

Gender
Both

Phase
N/A

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
Tehran University of Medical Science - vice-chancellor for research

Street address
Next to milad tower-hemmat highway

City
Tehran

Postal code

Approval date
2009-02-17, 1387/11/29

Ethics committee reference number
4291

Health conditions studied

1

Description of health condition studied
lower leg fracture

ICD-10 code
S82-7

ICD-10 code description
Multiple fractures of lower leg

Primary outcomes

1

Description
pain after leg fracture surgery

Timepoint
immediately at the end of operation - 2,4,6h after surgery

Method of measurement
visual analogue scale , 1 to 10

Secondary outcomes

1

Description
time of analgesic request by the patient

Timepoint
the first time patient asked for analgesuic

Method of measurement
hour after surgery

2

Description
amount of opium injected to patient during 24 h

Timepoint
at the end of first day after surgery

Method of measurement
miligram of opium consumpted

Intervention groups

1

Description
no premedication

Category
N/A

2

Description
200 mg celecoxib the night before surgery and 200 mg in the morning

Category
Prevention

3

Description
400mg celecoxib night before surgery

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital
Full name of responsible person
Street address
City
Tehran

2

Recruitment center
Name of recruitment center
Rasool Akram Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Science
Full name of responsible person
Jafarpour
Street address
Next to milad tower - Hemmat highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Science
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Science
Full name of responsible person
Alireza Pournajafian
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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