Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparision the effect of morphine infusion with IV PCA and interathecal morphine in postop pain of tibia fracture

Protocol summary

Summary

Purpose of Study: comparison the effect of morphine infusion withIV PCA and interathecal morphin in postop pain of tibia fracture. Study: randomized; double blind ; placebo; one central; phase II trial; Inclusion criteria : age between 20 to 50 years old; ASA I,II. Exclusion criterion: addiction to substance. Interventoinal in study: in this study patient divided to two groups. The first group recevived spinal anesthesia with morphine and another group IV PCA with morphine. Time of interventions: the first Group in time of spinal and the second grop after spinal intravenous morphine using .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013051513340N1**
Registration date: **2014-04-13, 1393/01/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-13, 1393/01/24

Registrant information

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Abolghasem Ahmadvand
Name of organization / entity
Qazvin University Of Medical Science
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Qazvin University of Medical Sciences

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2013-11-06, 1392/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision the effect of morphine infusion with IV PCA and interathecal morphine in postop pain of tibia fracture

Public title

Comparision the effect of morphine infusion with IV PCA and interathecal morphine in postop pain of tibia fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : age between 20 to 50 years old; ASA I,II. Exclusion criterion: addiction to substance.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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 Qazvin University of Medical Science
Street address
Navab Avenue ; Qazvin University of Medical Science
City
Qazvin
Postal code
Approval date
2013-02-05, 1391/11/17
Ethics committee reference number
28/20/6889

Health conditions studied

1

Description of health condition studied
Painless after administraion of morphin
ICD-10 code
T40.2
ICD-10 code description
Other opioids Morphine

Primary outcomes

1

Description
Appointment amount of painless with interatecal of morphin
Timepoint
After Spinal Anesthesia any one hour for 12 hour
Method of measurement
Method of Visual analog scale

Secondary outcomes

1

Description
Measure outcome amount of nausia and vomitting in tow Group
Timepoint
After spinal anesthesia every one Hour for 12 hours
Method of measurement
Check list and existing vomiting and nausia

2

Description
Amount of itching
Timepoint
After spinal anesthesia every one Hour for 12 hours
Method of measurement
Check list and existing itching or not

3

Description
Measuring changing heart rate and blood pressure
Timepoint
After spinal anesthesia every one Hour for 12 hours
Method of measurement
Check list

Intervention groups

1

Description
In this group pationt under spinal anesthesia with 3 cc Marcain 0.5 precentage and 0.2 miligram morphin interathecal and amount of painless and amount of itching and nausia and vomitting and changing heart rate and boold pressure every one houre for 12 houre mesuring
Category
Treatment - Drugs

2

Description
In the control group pationt under spinal anesthesia with 3 CC Marcain 0.5 precentage and 1 cc free water interathecal and amount of painless and amount of itching and nausia and vomitting and changing heart rate and boold pressure every one houre for 12 houre mesuring
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rajaee Hospital, Qazvin
Full name of responsible person
Abolghasem Ahmadvand
Street address
Rajee Hospital ; Padegan Avenu ; Qzvin
City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Qazvin University of Medical Sciences
Full name of responsible person
Mahnaz Abbasi
Street address
Qazvin University of Medical Sciences; Navab Avenue
City
Qazvin
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, Qazvin 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