

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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 with IV 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

Name

Abolghasem Ahmadvand

Name of organization / entity

Qazvin University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 28 1333 7006

Email address

aahmadvand@qums.ac.ir

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 administration of morphine

ICD-10 code

T40.2

ICD-10 code description

Other opioids Morphine

Primary outcomes

1

Description

Appointment amount of painless with interatecal of morphine

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 nausea and vomiting in tow Group

Timepoint

After spinal anesthesia every one Hour for 12 hours

Method of measurement

Check list and existing vomiting and nausea

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 patient under spinal anesthesia with 3 cc Marcain 0.5 percentage and 0.2 miligram morphine interathecal and amount of painless and amount of itching and nausea and vomiting and changing heart rate and blood pressure every one hour for 12 hours measuring

Category

Treatment - Drugs

2

Description

In the control group patient under spinal anesthesia with 3 CC Marcain 0.5 percentage and 1 cc free water interathecal and amount of painless and amount of itching and nausea and vomiting and changing heart rate and blood pressure every one hour for 12 hours measuring

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajae Hospital, Qazvin

Full name of responsible person

Abolghasem Ahmadvand

Street address

Rajee Hospital ; Padegan Avenue ; Qazvin

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**

Qazvin University of Medical Sciences

Full name of responsible person

Abolghasem Ahmadvand

Position

Resident of Anesthesia

Other areas of specialty/work**Street address**

Qazvin University of Medical Sciences; Navab Avenue

City

Qazvin

Postal code**Phone**

+98 28 1333 5800

Fax**Email**

aahmadvand@qums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Abolghasem Ahmadvand

Position

Resident of Anesthesia

Other areas of specialty/work**Street address**

Qazvin University of Medical Sciences; Navab Avenue

City

Qazvin

Postal code**Phone**

+98 28 1333 5800

Fax**Email**

aahmadvand@qums.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Abolghasem Ahmadvand

Position

Resident of Anesthesia

Other areas of specialty/work**Street address**

Qazvin University Of Medical Sciences; Navab Avenue

City

Qazvin

Postal code**Phone****Fax****Email**

aahmadvand@qums.ac.ir

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