

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of ketorolac and pethidine on analgesia and drug use after lower limb orthopedic surgery by spinal anesthesia

Protocol summary

Study aim

Comparison of the effect of ketorolac and pethidine on analgesia and drug use after lower limb orthopedic surgery by spinal anesthesia

Design

The present study was a double-blind randomized clinical trial with parallel groups on 60 patients who were randomly divided into two groups by Throwing coins .

Settings and conduct

This double-blind randomized clinical trial study was performed on 60 patients who underwent lower limb orthopedic surgery (femur and tibia) in the orthopedic operating room of Peymaniyeh Hospital in Jahrom. Patients were randomly divided into two groups: pethidine and ketorolac. The study participant, the researcher, and the data collector were unaware of which group the individuals belonged to.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients are candidates for lower limb orthopedic surgery who undergo spinal anesthesia during the procedure. Exclusion criteria: Hemodynamic instability, bradycardia or tachycardia, and other complications whose continued presence in the study poses potential risk to life were excluded from the study.

Intervention groups

The first group is patients who receive 30 mg of pethidine intravenously. The second group is patients who receive 60 mg of ketorolac intravenously.

Main outcome variables

the pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200728048244N1**

Registration date: **2020-08-17, 1399/05/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-17, 1399/05/27**

Update count: **0**

Registration date

2020-08-17, 1399/05/27

Registrant information

Name

Ameneh Ranjbar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4244 2348

Email address

samira.rb24@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-29, 1398/12/10

Expected recruitment end date

2020-08-31, 1399/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of ketorolac and pethidine on analgesia and drug use after lower limb orthopedic surgery by spinal anesthesia

Public title

Comparison of ketorolac and pethidine in analgesia after orthopedic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Lower limb fractures

Exclusion criteria:
History of drug addiction History of migraine Inability to communicate properly with the patient to evaluate postoperative pain Need to be admitted to the ICU after surgery Patients in ASA class 2

Age
From **15 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients participating in the present study were divided into two groups by tossing coins.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study participant, the researcher, and the data collector were unaware of which group the individuals belonged to.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Jahrom University of Medical Sciences

Street address

Jahrom University of Medical Sciences, Motahhari Blvd, Jahrom

City

Jahrom

Province

Fars

Postal code

7167758256

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR.JUMS.REC.1397.149

Health conditions studied

1

Description of health condition studied

Pain in orthopedic patients

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

the pain

Timepoint

After surgery, first in recovery at zero hours, then at 6, 12, 18 and 24 hours after surgery

Method of measurement

pain assessment ruler

Secondary outcomes

1

Description

Vital signs

Timepoint

In minutes 5, 10, 20 and 60, 90 and 120

Method of measurement

monitoring

Intervention groups

1

Description

Intervention group1: They receive 30 mg of pethidine intravenously

Category

Treatment - Drugs

2

Description

Intervention group2:They receive 30 mg of ketorolac intravenously

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Peymanieh Hospital, Jahrom city
Full name of responsible person
 Navid Kalani
Street address
 Jahrom, Shahid Motahhari Boulevard, Peymaniyeh Hospital
City
 Jahrom
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Postal code
 71677251542
Phone
 +98 71 3525 5652
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 Navidkalani@ymail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
 Jahrom University of Medical Sciences
Full name of responsible person
 Solh Ju Kavos
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 Vice chancellor for research, Jahrom University of Medical Sciences, Motahhari Blvd, Jahrom
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 navidkalani@ymail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Jahrom University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Jahrom University of Medical Sciences
Full name of responsible person
 Samira Ranjbar
Position
 medical student
Latest degree
 Medical doctor
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 General Practitioner
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Person responsible for updating data

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available