Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Province
Fars
Postal code
71677251542
Phone
+98 71 3525 5652
Email
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
Street address
Vice chancellor for research, Jahrom University of Medical Sciences, Motahhari Blvd, Jahrom
City
Jahrom
Province
Fars
Postal code
7167758256
Phone
+98 71 2536 5231
Email
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
Other areas of specialty/work
General Practitioner
Street address
Jahrom University of Medical Sciences, Motahhari Blvd, Jahrom
City
Jahrom
Province
Fars
Postal code
7167758256
Phone
+98 71 2536 5231
Email
samira.rb24@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
navid kalani
Position
Research employee
Latest degree
Master
Other areas of specialty/work
Anesthesiology
Street address
Jahrom University of Medical Sciences, Motahhari Blvd, Jahrom
City
Jahrom
Province
Fars
Postal code
7167758256
Phone
+98 71 2536 5231
Email
k.navid@jums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
Samira Ranjbar
Position
medical student
Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner
Street address
Jahrom University of Medical Sciences, Motahhari Blvd, Jahrom
City
Jahrom
Province
Fars
Postal code
7167758256
Phone
+98 71 2536 5231
Email
samira.rb24@gmail.com

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