Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

comparsion of hemodynamic changes in elderly patients undergoing orthopedic surgery of the lower limbs in tow ways subarachnoid bupivacain and subarachnoid meperidin

Protocol summary

Summary

This study will be done with aim to comparative investigation of hemodynamic changes in elderly patients undergoing orthopedic surgery of the lower limbs in two subarachnoid bupivacain and subarachnoid meperidin ways. This study is one-blinded clinical trial. The study population will be included all elderly patients undergoing orthopedic surgery of the lower limbs at least one year in Imam Reza and Taleghani hospitals of Kermanshah. The total of 66 patients will be selected in available method and randomly will be assigned in to two experimental groups. In the first group anesthesia with bupivacaine spinal, the patient is placed in a sitting position and by spinal needle number 15-25,12.5-24 mg of bupivacaine half percent (0.5 %) (2.5 ml) in subarachnoid space (between vertebrae 12-13and 13-14) injection is done. In the second group the patient is placed in a sitting position and by spinal needle number 24-25 pethidine With the dose of 1 mg plus 2 ml csf in the subarachnoid space (between the vertebrae l2-l3 and l3-l4) will be injected. First, during, and after the end of the study, both groups are compared in terms of hemodynamic changes. Inclusion criteria: Age over 60 years; Patients of class 1 and 2 ASA-PS. Exclusion criteria: Patients who consume narcotic drugs and psychotropic substances; patients generally have a contraindication to spinal procedures; Patients who experience severe pain during the surgery and have to use general anesthesia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031414333N71**
Registration date: **2017-04-06, 1396/01/17**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-04-06, 1396/01/17

Registrant information

Name
Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2017-05-10, 1396/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparsion of hemodynamic changes in elderly patients undergoing orthopedic surgery of the lower limbs in tow ways subarachnoid bupivacain and subarachnoid meperidin

Public title
Comparison of changes in blood pressure and heart rate in patients undergoing orthopedic surgery of the lower limbs in two anesthesia method.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age over 60 years; Patients of class 1 and 2 ASA-PS. Exclusion criteria: Patients who consume narcotic drugs and psychotropic substances; patients generally have a contraindication to spinal procedures; Patients who experience severe pain during the surgery and have to use general anesthesia.
Age
From **60 years** old to **100 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Building No.2, ShahidBeheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Postal code
Approval date
2017-03-08, 1395/12/18
Ethics committee reference number
kums.rec.1395.759

Health conditions studied

1

Description of health condition studied
Fracture of Lower Limb
ICD-10 code
T12
ICD-10 code description
Fracture of lower limb, level unspecified

Primary outcomes

1

Description
Itching
Timepoint
First, during, and after the end of the study
Method of measurement
Based on patient interview

2

Description
Nausea and vomiting
Timepoint
First, during, and after the end of the study
Method of measurement
Based on patient interview

3

Description
Urinary retention
Timepoint
First, during, and after the end of the study
Method of measurement
Based on patient interview

4

Description
Respiratory depression
Timepoint
First, during, and after the end of the study
Method of measurement
Based on the questions of the patient and a doctor diagnoses

5

Description
Duration of analgesia
Timepoint
The first, second, third, fourth, fifth, sixth hours after the start of the study
Method of measurement
Based on the questions of the patient and a doctor diagnoses

6

Description
Hemodynamic changes

Timepoint
First, during, and after the end of the study
Method of measurement
Based on manometer and monitor

Secondary outcomes

empty

Intervention groups

1

Description
In the first group anesthesia with bupivacaine spinal, the patient is placed in a sitting position and by spinal needle number 15-25,12.5-24 mg of bupivacaine half percent (0.5 %) (2.5 ml) in subarachnoid space (between vertebrae 12-13and 13-14) injection is done.
Category
Treatment - Drugs

2

Description
In the second group the patient is placed in a sitting position and by spinal needle number 24-25 pethidine with the dose of 1 mg plus 2 ml csf in the subarachnoid space (between the vertebrae l2-l3 and l3-l4) will be injected.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Dr. Hamzeh Hasani
Street address
Taleghani Hospital, Shahid Beheshti Blvd
City
Kermanshh

2

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Dr. Hamzeh Hasani
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshh

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences
Full name of responsible person
Koroush Hamzehee
Street address
Building No.2, ShahidBeheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
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, Kermanshah 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
Kermanshah University of Medical Sciences
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Position
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Person responsible for updating data

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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