Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of Dexmedetomidine and Fentanyl effect in change of hemodynamic response and block characters after spinal anesthesia with Ropivacaeen in lower limb fracture

Protocol summary

Study aim
Comparison of Dexmedetomidine and Fentanyl effect in change of hemodynamic response and block characters after spinal anesthesia with Ropivacaeen in lower limb fracture

Design
This study is clinical trial and double blind. patients will be divided in 2 groups by simple randomization.Groups are parallel.

Settings and conduct
Patients candidate for femoral orthopedic surgery in Valiasr hospital in Arak will enter this study. Outcome assessor and analyzer don't aware from grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria:ASA class 1 and 2, patients undergoing femoral orthopedic surgery, failure to perform spinal anesthesia, no history of taking beta-blockers and alpha-2 calcium channel blockers and blockers, lack of cardiovascular problems, no pregnancy, absence of coagulation disorders Exclusion criteria:patient dissatisfaction, blocks failed, surgical operations more than 120 minutes, patients who have heart-respiratory arrhythmia during operation

Intervention groups
First group: injection of 5 microgram Dexmedetomidine plus 3-4 milliliter Ropivacaeen (15-20 milligram) (Hospira Co.America). Second group: injection of 20 microgram Fentanyl plus 3-4 milliliter Ropivacaeen (15-20 milligram) (Hospira Co.America).

Main outcome variables
blood pressure; heart rate; oxygen saturation; pain; duration of motor and sensory block; narcotic drug consumption

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141209020258N115**
Registration date: **2019-07-07, 1398/04/16**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-07, 1398/04/16**
Update count: **0**

Registration date
2019-07-07, 1398/04/16

Registrant information

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Name of organization / entity
Arak University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2020-04-20, 1399/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of Dexmedetomidine and Fentanyl effect in change of hemodynamic response and block characters after spinal anesthesia with Ropivacaeen in lower limb fracture

Public title
Comparing the effect of Dexmedetomidine and Fentanyl in change of hemodynamic response and block characters after spinal anesthesia with Ropivacaeen in lower limb fracture

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
ASA class 1 and 2 Patients undergoing femoral orthopedic surgery Lack of failure to perform spinal anesthesia No history of taking beta-blockers and alpha-2 calcium channel blockers and blockers Lack of cardiovascular problems No pregnancy Absence of coagulation disorders Non-localized infection in the spinal cord Absence of mental and psychological problems Lack of peripheral and central neuropathy

Exclusion criteria:
Patient dissatisfaction Blocks failed Surgical operations more than 120 minutes Patients who have heart-respiratory arrhythmia during operation

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization with randomization with envelopes in two groups A and B . In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping.The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics comittee of Arak University of Medical Sciences

Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,Sardasht,Arak

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2019-04-07, 1398/01/18

Ethics committee reference number
IR.ARAKMU.REC.1398.028

Health conditions studied

1

Description of health condition studied
Femure fracture

ICD-10 code
S72.0

ICD-10 code description
Fracture of neck of femur

Primary outcomes

1

Description
Mean arterial blood pressure

Timepoint
In the first 15 minutes every 5 minutes, then at minutes 30, 60, 45, 90

Method of measurement
Barometer

2

Description
Heart rate

Timepoint
In the first 15 minutes every 5 minutes, then at minutes 30, 60, 45, 90

Method of measurement
Count

3

Description
Percent of oxygen saturation
Timepoint
In the first 15 minutes every 5 minutes, then at minutes 30, 60, 45, 90
Method of measurement
Pulse oximetry

4

Description
Duration of motor block
Timepoint
Every 5 minute
Method of measurement
Minute

5

Description
Duration of Sensory block
Timepoint
Every 5 minutes
Method of measurement
Minute

6

Description
Pain
Timepoint
At recovery and 2 and 4 and 8 postoperative
Method of measurement
Visual Analogue Scale Questionnaire

7

Description
Mean of narcotic
Timepoint
24 hour after surgery
Method of measurement
Milligram

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: We inject 5 microgram Dexmedetomidine plus 3-4 milliliter Ropivacaeen(15-20 milligram)(Hospira Co.America).
Category
Treatment - Drugs

2

Description
Intervention group2: We inject 20 microgram Fentanyl plus 3-4 milliliter Ropivacaeen(15-20 milligram)(Hospira Co.America).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Dr Alireza Kamali
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Shirin Pazuki

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Kamali

What processes are involved for a request to access

data/document

They have to write letters to the professors and the university

Comments