

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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 Ropivacaen in lower limb fracture	Not used Assignment Parallel Other design features
Public title Comparing the effect of Dexmedetomidine and Fentanyl in change of hemodynamic response and block characters after spinal anesthesia with Ropivacaen in lower limb fracture	Secondary Ids empty
Purpose Treatment	Ethics committees
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	1 Ethics committee Name of ethics committee Ethics committee of Arak University of Medical Sciences Street address Ethics committee, Research center, Payambar Azam complex, Basij squire ,Sardasht,Arak City Arak Province Markazi Postal code 3848176941
Age From 18 years old to 60 years old Gender Both	Approval date 2019-04-07, 1398/01/18 Ethics committee reference number IR.ARAKMU.REC.1398.028
Phase 2-3 Groups that have been masked • Participant • Outcome assessor • Data analyser	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
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.	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
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	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

Name of organization / entity

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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
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Full name of responsible person
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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