

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison the effect of bupivacaine-dexmedetomidine with bupivacaine-fentanyl on block characteristics of selective spinal anesthesia in patients undergoing leg surgery.

Protocol summary

Sensory block in dependent and non dependent limb.

Study aim

Evaluation and comparison of block characteristics of selective spinal anesthesia by three different drug regimen: Bupivacaine-fentanyl, Bupivacaine-dexmedetomidine, and lone Bupivacaine .

Design

In this study 90 eligible patients candidates for calf surgery will be divided into three study groups randomly , and a code will be assigned to each patient .

Settings and conduct

The research will be conducted at Kawsar Hospital of Sanandaj. After prehydration and connecting standard monitoring , basic value of BP, HR , and SpO2 are recorded. Then patient will be turned to lateral position such that the depending side be in downward . After prep and drep and using sterility method spinal anesthesia will be done using Queincke needle 25G .The bevel of needle will be turned to inferior side after appearing the clear CSF , the drug that has been prepared by anesthetic nurse will be injected intrathecally by 0.2 ml/sec speed. Patient will be in lateral position for 10 minute and then turn to supine. Study outcomes will be evaluated by a colleague who will be blinded to patient grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: writing informed consent sheet , American Society of Anesthesiologist Physical Status 1- 3 . Exclusion criteria : History of allergy to study drugs, history of lower limb neuropathy. history of infection of injection site in lumbar region, any contraindication of spinal anesthesia, and hypovolemia.

Intervention groups

1: Bupivacaine 5mg-fentanyl 5 microgram
2: Bupivacaine 5mg-dexmetomidine 5 microgram
3: Bupivacaine alone.

Main outcome variables

Motor block in dependent and non dependent limb.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161031030601N2**

Registration date: **2018-02-28, 1396/12/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-28, 1396/12/09**

Update count: **0**

Registration date

2018-02-28, 1396/12/09

Registrant information

Name

naseh taheberaneh

Name of organization / entity

kurdestan medical univercity

Country

Iran (Islamic Republic of)

Phone

+98 87 3366 4657

Email address

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Recruitment status

Recruitment complete

Funding source

25000000r

Expected recruitment start date

2018-02-04, 1396/11/15

Expected recruitment end date

2019-02-04, 1397/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of bupivacaine-dexmedetomidine with bupivacaine-fentanyl on block characteristics of selective spinal anesthesia in patients undergoing leg surgery.

Public title

Effects of different drugs on block characteristics of selective spinal anesthesia.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Writing Informed consent American society anesthesiologists physical status 1-3 Site of surgery under knee

Exclusion criteria:

History of allergy to study drugs. History of lower limb neuropathy. local sepsis of needle insertion site History of coagulopathy. Any contraindication of spinal anesthesia. Hypovolemia.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomisation will be done by one of researchers who is not involved in patient evaluation and anesthesia procedure. This will be done based on computer-generated-numbers. So, we would have 90 envelopes numbered from 1 to 90, and we will put a folded sheet contain the name of one of 3 study groups, so that it couldn't be readable from outside. Based on the sheet in serial envelopes patient will be entered to one of 3 study groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both patients and researcher colleague who evaluate and collect study outcomes are blinded about patient groups and combination of drugs that will be injected intrathecally.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee of Kurdistan University of Medical Science

Street address

Faculty of Medicine , Pasdaran BLV

City

Sanandaj.

Province

Kurdistan

Postal code

6618634683

Approval date

2016-09-22, 1395/07/01

Ethics committee reference number

IR.MUK.REC.1395/164

Health conditions studied**1****Description of health condition studied**

Spinal Anaesthesia

ICD-10 code

R20.0

ICD-10 code description

Neuraxial anesthesia , Spinal Anaesthesia

Primary outcomes**1****Description**

Motor block

Timepoint

6h-12h-24h after surgery

Method of measurement

Bromage Scale

2**Description**

Duration of sensory block.

Timepoint

Duration of sensory block will be measured by differences between initiation of loss of sensation to pinprick and return of sensation in sacral region.

Method of measurement

Pinprick test.

Secondary outcomes

1

Description

Pain after surgery.

Timepoint

24h after surgery

Method of measurement

Based on Pain Visual Analogue Scale (VAS) which is a scale for measurement the intensity of pain.

Intervention groups

1

Description

In the first intervention group, 5 mg of 0.5% bupivacaine in combination with 5 µg fentanyl, which its volume is brought to 2 ml by adding normal saline, injected into L3-L4 or L4-L5 subarachnoid space in lateral position by a 25G spinal needle.

Category

Treatment - Drugs

2

Description

In the second intervention group, 5 mg of 0.5% bupivacaine in combination with 5 µg dexmedetomidine which its volume is brought to 2 ml by adding normal saline, injected into L3-L4 or L4-L5 subarachnoid space in lateral position by a 25G spinal needle.

Category

Treatment - Drugs

3

Description

In control group, 5 mg of 0.5% bupivacaine which its volume is brought to 2 ml by adding normal saline, injected into L3-L4 or L4-L5 subarachnoid space in lateral position by a 25G spinal needle.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kawsar hospital.

Full name of responsible person

Behzad Ahsan

Street address

Pasdarán Blvd.

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Sanandaj.

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Email

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Web page address

<http://www.muk.ac.ir/Muk/Hospitals/kawsar.aspx>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Ebrahim Ghaderi

Street address

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Web page address

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Grant name

IR-REC-1395/164

Grant code / Reference number

IR-REC-1395/164

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

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Karim Nasseri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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bihoshi@gmail.com

Web page address<http://www.muk.ac.ir/Muk/Faculties/pezeshki.aspx>

Resident of anesthesia

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Pasadena Blv, Kurdistan university of medical science.

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Web page address<http://www.muk.ac.ir/Muk/Faculties/pezeshki.aspx>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

Full name of responsible person

Karin Nasser

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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bihoshi@gmail.com

Web page address<http://www.muk.ac.ir/Muk/Faculties/pezeshki.aspx>**Person responsible for updating data****Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

Full name of responsible person

Naseh Taherbaneh

Position**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

All data s including primary and secondary outcomes , study results , and method of analysis will be published at the end of study.

When the data will become available and for how long

1/4/2019

To whom data/document is available

Scholars and academic and scientific institutions

Under which criteria data/document could be used

All scholars and academic centers could request access to data and will be able to use it , if mentioning the source.

From where data/document is obtainableKarim Nasser, Department of Anesthesia. Kasar Hospital , Pasdaran BLVD. Sanandaj, Iran. Tel:00988733660733
Email : bihoshi@gmail.com**What processes are involved for a request to access data/document**

We will try to answer to all requests s for data s in two week.

Comments