Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

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

Protocol summary

Study aim

Evaluation and comparison of block characteristics of selective spinal anesthesia by three different drug regimen:Bupivacaine-fentanyl,Bupivacaine-dexmedtomidine,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 Queinke 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:Bupivacaine5mg-fentanyl 5microgram 2:Bupivacaine5mg-dexmetomidine 5 microgram 3: Bupivacaine alone.

Main outcome variables

Motor block in dependent and non dependent limb.

Sensory 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 taherbaneh

Name of organization / entity

kurdestan medical univercity

Country

Iran (Islamic Republic of)

Phone

+98 87 3366 4657

Email address

n.taherbaneh@muk.ac.ir

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-fentanyle on block characeristics 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 conscent American socity anesthesilogists physical status1-3 Site of surgery under knee
Exclusion criteria:
History of alergy 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 envelop 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 envelops 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 Committe of Kurdestan 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 initation of loss of sensation to pinprik and return of sensation in sacral region.
Method of measurement
Pinprik test.

Secondary outcomes

1

Description
Pain after surgery.
Timepoint
24h after surgery
Method of measurement
Based on Pain Visual Analogue Scale (VAS) witch 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 dexmedtomidine 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
Pasdaran Blvd.
City
Sanandaj.
Province
Kurdistan
Postal code
6691733399
Phone
+98 87 3361 1232
Fax
+98 87 3361 1231
Email
b.ahsan@muk.ac.ir
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
Pasdaran Blv.
City
Sanandaj.
Province
Kurdistan
Postal code
6691733399
Phone
+98 87 3366 4645
Fax
+98 87 3366 4645
Email
ebrahimghaderi@yahoo.com
Web page address
http://research.muk.ac.ir/_Pages/Default.aspx
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
Street address
Pasdaran Blv.Kurdestan university of medical science.
City
Sanandaj
Province
Kurdistan
Postal code
6617933-9335
Phone
+98 87 3366 4657
Fax
+98 87 3366 4657
Email
bihoshi@gmail.com
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 Nasseri
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Pasdaran Blv.Kurdestan university of medical science.
City
Sanandaj
Province
Kurdistan
Postal code
6617939335
Phone
+98 87 3366 4657
Fax
+98 87 3366 4657
Email
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
Resident of anesthesia
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Pasadena Blv, Kurdestan university of medical science.
City
Sanandaj.
Province
Kurdistan
Postal code
6617939331
Phone
+98 87 3366 4645
Fax
+98 87 3366 4645
Email
n.taherbaneh@muk.ac.ir
Web page address
http://www.muk.ac.ir/Muk/Faculties/pezeshki.aspx

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 obtainable
Karim Nasseri, 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