Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative study of epidural and spinal anesthesia on ventricular repolarization in patients undergoing elective lower limb surgery

Protocol summary

Study aim
prevention
Design
In this study, 60 patients undergoing elective lower limb surgery were divided into two groups. In the first group, spinal anesthesia was performed through L4-L5, L3-L4 with bupivacaine and in the intervention group, epidural anesthetic from L3-L4 or L4-L5 space with Bupivacaine . After surgery, the QT interval is evaluated in the patient's electrocardiogram.
Settings and conduct
Clinical trial; Kashani Hospital
Participants/Inclusion and exclusion criteria
Inclusion criteria: the QTc interval is less than 440 milliseconds in the pre-operative electrocardiogram
Exclusion criteria:treated with antiarrhythmic drugs; are treated with QTc interval augmenting drugs; history of cardiac disease; electrolyte imbalance
Intervention groups
In the first group, spinal anesthesia are performed through L4-L5, L3-L4 with bupivacaine and in the intervention group epidural anesthesia from L3-L4 or L4-L5 space with bupivacaine.
Main outcome variables
QT spacing of the electrocardiogram

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190120042427N1**
Registration date: **2019-02-14, 1397/11/25**
Registration timing: **prospective**

Last update: **2019-02-14, 1397/11/25**
Update count: **0**
Registration date
2019-02-14, 1397/11/25

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-02-20, 1397/12/01
Expected recruitment end date
2019-07-23, 1398/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of epidural and spinal anesthesia on ventricular repolarization in patients undergoing elective lower limb surgery

Public title
Comparative study of epidural vs. spinal anesthesia on ventricular repolarization in patients undergoing lower limb surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
The QTc interval is less than 440 milliseconds in the pre-

operative electrocardiogram

Exclusion criteria:

Treated with antiarrhythmic drugs Are treated with QTc interval augmenting drugs History of cardiac disease Electrolyte imbalance

Age

From **60 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified Random Sampling،Randomization was performed using software and permutable blocks, in which the blocks were 4 and the number was respectively the lowest and the highest in the fourth and first group, and then the third and the second group respectively.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient is not aware of the kind of intervention

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Vice Chancellor of Research and Technology , Shahrekord University of Medical Sciences, Kashani Blvd, Shahrekord,Iran

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Province

Chahar-Mahal-va-Bakhtiari

Postal code

8818718788

Approval date

2016-05-09, 1395/02/20

Ethics committee reference number

IR.SKUMS.REC.1395.41

Health conditions studied

1

Description of health condition studied

surgery operation

ICD-10 code

Y60.0

ICD-10 code description

During surgical operation

Primary outcomes

1

Description

QT spacing of the electrocardiogram

Timepoint

after surgery

Method of measurement

electrocardiogram

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: epidural anesthesia done from L3-L4 or L4-L5 space with bupivacaine injection.

Category

Prevention

2

Description

Control group: In the first group, spinal anesthesia was performed through L4-L5, L3-L4 with bupivacaine.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Mahmoud Akhlaghi

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Kashani Hospital of Shahrekord University of Medical Sciences, ParastarAvenue,Shahrekord, Iran

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Sponsors / Funding sources

1

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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
Shahre-kord 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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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Patient file information
When the data will become available and for how long
six month
To whom data/document is available
Researchers working in academia and academia
Under which criteria data/document could be used
article
From where data/document is obtainable
journal
What processes are involved for a request to access data/document
publication of article
Comments