

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Sep 2026

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

Protocol summary

2019-02-14, 1397/11/25

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

Registrant information

Name

Amin Panahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

Email address

aminpanahi@skums.ac.ir

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-

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

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

City

Shahrekord

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

Street address

Kashani Hospital of Shahrekord University of Medical Sciences, Parastar Avenue, Shahrekord, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
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Vice Chancellor of Research and Technology
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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
Shahre-kord University of Medical Sciences
Full name of responsible person
Mahmoud Akhlaghi
Position
Anesthesiology
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Person responsible for updating data

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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