

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 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

#### 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

#### 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-

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

**City**

shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8818718796

**Phone**  
+98 38 3222 0016  
**Email**  
akhlaghi23@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Shahre-kord University of Medical Sciences  
**Full name of responsible person**  
Dr. Kamal Solati  
**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**  
8815713471  
**Phone**  
+98 38 3222 0016  
**Email**  
solati@skums.ac.ir

#### 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  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Kashani Hospital of Shahrekord University of Medical

Sciences, Parastar Avenue, Shahrekord, Iran  
**City**  
shahrekord  
**Province**  
Chahar-Mahal-va-Bakhtiari  
**Postal code**  
8818718796  
**Phone**  
+98 38 3222 0016  
**Email**  
akhlaghi23@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Shahre-kord University of Medical Sciences  
**Full name of responsible person**  
Mahmoud Akhlaghi  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Kashani Hospital of Shahrekord University of Medical  
Sciences, Parastar Avenue, Shahrekord, Iran  
**City**  
shahrekord  
**Province**  
Chahar-Mahal-va-Bakhtiari  
**Postal code**  
8818718796  
**Phone**  
+98 38 3222 0016  
**Email**  
akhlaghi23@yahoo.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Shahre-kord University of Medical Sciences  
**Full name of responsible person**  
Mahmoud Akhlaghi  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Kashani Hospital of Shahrekord University of Medical  
Sciences, Parastar Avenue, Shahrekord, Iran  
**City**  
shahrekord  
**Province**  
Chahar-Mahal-va-Bakhtiari  
**Postal code**  
8818718796

**Phone**

+98 38 3222 0016

**Email**

akhlaghi23@yahoo.com

**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**