

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of the effect of spinal anesthesia and general anesthesia on inflammatory cytokines following ischemic changes caused by tourniquet reperfusion in lower extremity surgery

Protocol summary

Study aim

To compare the effect of spinal anesthesia and general anesthesia on inflammatory cytokines following ischemic changes caused by tourniquet reperfusion in lower extremity surgery

Design

A total of 52 patients in need of surgery, admitted to Imam Reza Hospital of Birjand, who are eligible to enter the study are selected and assigned to spinal anesthesia or general anesthesia groups via simple randomization methods.

Settings and conduct

The study will be performed in the operating room of Imam Reza Hospital in Birjand.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. ASA grade I or II 2. Age range of 25 to 65 years 3. Use of tourniquet on the lower limbs of one side 4. Absence of vascular disease 5. No cardiorespiratory disease Exclusion Criteria: 1. Duration of surgery less than 60 minutes or more than 90 minutes 2. Need for re-operation 3. Patient's unwillingness to cooperate in each stage of study 4. Patient's death

Intervention groups

There are two intervention groups in this study. In the spinal anesthesia, a blood sample will be collected before anesthesia, and the patient will undergo spinal anesthesia. In the general anesthesia group, a blood sample will be collected before anesthesia and then the patient will undergo general anesthesia. Before surgery and 12 and 48 hours after surgery, blood samples will be collected in both groups.

Main outcome variables

IL-6 will be tested by an enzyme-linked immunosorbent assay. TNF alpha, hs-CRP, and ferritin will be determined using laboratory kits in the laboratory.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150308021383N10**

Registration date: **2018-02-11, 1396/11/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-11, 1396/11/22**

Update count: **0**

Registration date

2018-02-11, 1396/11/22

Registrant information

Name

Amir Saber Tanha

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3243 2778

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dr.saber@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Birjand University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of spinal anesthesia and general anesthesia on inflammatory cytokines following ischemic changes caused by tourniquet reperfusion in lower extremity surgery

Public title
General or spinal anesthesia for lower limb surgeries with tourniquet

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
ASA grade I or II Age range of 25 to 65 years use of tourniquet on the lower limbs of one side absence of vascular disease no cardio respiratory disease absence of renal failure non-impairment in liver function non-diabetes or the use of any antioxidant or anti-inflammatory drug
Exclusion criteria:
Duration of surgery less than 60 minutes or more than 90 minutes Need for re-operation patient's unwillingness to cooperate in each stage of study patient's death

Age
From **25 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants will be allocated into one of the two study groups via simple randomization method and will receive the intervention of the group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Outcome assessor and care providers were blind to the allocation groups of participants.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Birjand University of Medical Sciences

Street address

Vice-chancellery for Research, Birjand University of Medical Sciences, Ghaffari Ave.

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2017-10-16, 1396/07/24

Ethics committee reference number

lr.bums.REC.1396.178

Health conditions studied

1

Description of health condition studied

lowerlimb surgery

ICD-10 code

M84

ICD-10 code description

Disorders of continuity of bone

Primary outcomes

1

Description

serum level of Interlukin 6

Timepoint

Before using tourniquet (T0), 12 hours after surgery (T1), and 48 hours after surgery (T2)

Method of measurement

ELISA

2

Description

TNFA

Timepoint

Before using tourniquet (T0), 12 hours after surgery (T1), and 48 hours after surgery (T2)

Method of measurement

ELISA

3

Description

hs-CRP

Timepoint

Before using tourniquet (T0), 12 hours after surgery (T1), and 48 hours after surgery (T2)

Method of measurement

ELISA

4

Description

ferritin

Timepoint

Before using tourniquet (T0), 12 hours after surgery (T1), and 48 hours after surgery (T2)

Method of measurement

ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1 (Spinal Anesthesia): A blood sample will be collected before anesthesia. The patient will undergo spinal anesthesia. Before surgery and 12 and 48 hours after surgery, blood samples will be collected.

Category

Treatment - Drugs

2

Description

Intervention Group 2 (General Anesthesia): A blood sample will be collected before anesthesia. The patient will undergo general anesthesia. Before surgery and 12 and 48 hours after surgery, blood samples will be collected.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr. Amir Sabertanha

Street address

Taleghani St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr. Tooba Kazemi

Street address

Birjand University of Medical Sciences, Ghafari Street, Birjand.

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dr.toobakazemi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Dr. Amir Sabertanha

Position

Assistant professor of anesthesia

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

As part of the informed consent, confidentiality is to be reserved.

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

In the potential paper extracted, such data will be shared.

When the data will become available and for how long

Upon acceptance of the potential paper and as long as the paper is available online.

To whom data/document is available

To all readers of the paper

Under which criteria data/document could be used

Upon conditions mentioned by the journal

From where data/document is obtainable

the journal

What processes are involved for a request to access data/document

Given the data available in the paper and correspondence with authors via email addresses mentioned in the paper

Comments