

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

A comparative study of the effects of two different methods of anesthesia on Hs-CRP blood level in patients undergoing lower extremity surgery

Protocol summary

Summary

The main objective of this study is comparing Hs-CRP level in two method of anesthesia in patients undergoing lower extremity surgery. This is a clinical trial on 60 male patients aged 40 to 60 and BMI between 20 to 25 who are candidate for lower extremity surgery (plaque removal). Inclusion criteria: lower extremity surgery; age 40 to 60 year; male sex. Exclusion criteria: polymyositis; neurological disorders; hepatic failure; diabetes (DM); malignancies; pulmonary hypertension; serum Cr above 2 mg/dl; platelet under 150,000; INR under 1.1; steroids consumption within last 6 months; multiple trauma patients. The patients are divided into 2 groups randomly by means of draw. In group A general anesthesia and in group B spinal anesthesia is performed. Before fluid administration, a blood sample is taken for measuring Hs-CRP. During anesthesia they are monitored and their blood pressure is recorded every 10 minutes. In recovery room and 30 minutes after arrival, another blood sample is sent for analysis and third sample will be taken the next day in the morning. Finally the effects of these methods on Hs-CRP level will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202067488N2**

Registration date: **2015-06-01, 1394/03/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-01, 1394/03/11

Registrant information

Name

Mohammadali Haghbin

Name of organization / entity

Kerman University of MedicalSciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kerman University of Medical sciences

Expected recruitment start date

2015-01-01, 1393/10/11

Expected recruitment end date

2015-06-01, 1394/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effects of two different methods of anesthesia on Hs-CRP blood level in patients undergoing lower extremity surgery

Public title

comparing the blood level of acute phase protein (Hs-CRP) in two methods of anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: lower extremity surgery; age 40 to 60 year; male sex. Exclusion criteria: polymyositis; neurologic disorders; hepatic failure; diabetes (DM); malignancies; pulmonary hypertension; serum Cr above

2 mg/dl; platelet under 150,000; INR under 1.1; steroids consumption within last 6 months; multiple trauma patients.

Age

From **40 years** old to **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of Kerman University of Medical Sciences

Street address

Shafa Square, Jomhoori Boulevard

City

Kerman

Postal code

Approval date

2015-01-21, 1393/11/01

Ethics committee reference number

k/93/536

Health conditions studied

1

Description of health condition studied

anaesthesia

ICD-10 code

T88.5

ICD-10 code description

Other complications of anaesthesia

Primary outcomes

1

Description

Hs-CRP blood level

Timepoint

before induction of anaesthesia, half an hour after admission to recovery room and next day

Method of measurement

blood anlysis

Secondary outcomes

1

Description

blood pressure

Timepoint

every 10 minutes

Method of measurement

automatic monitoring device

Intervention groups

1

Description

Performing lower extremity surgery under general anesthesia

Category

Treatment - Surgery

2

Description

Performing lower extremity surgery under spinal anesthesia

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa hospital

Full name of responsible person

Mohamad Ali Haghbin

Street address

Farabi Street, Shafa hospital

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Hassani
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 Tahmasbabad Square, Ebnesina Street
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 Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Vice chancellor for research, Kerman University of Medical Sciences
Proportion provided by this source
 100
Public or private sector
 empty
Domestic or foreign origin
 empty
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
 empty
Study Protocol
 empty
Statistical Analysis Plan
 empty
Informed Consent Form
 empty
Clinical Study Report
 empty
Analytic Code
 empty
Data Dictionary
 empty