

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of the effect of Spinal and General Anesthesia on Serum Lipid Peroxides and Total Antioxidant Capacity in Diabetic Patients with Lower Limb Amputation Surgery

Protocol summary

Summary

Propose: Comparison of spinal and general anesthesia on serum Lipid Peroxides and total antioxidant capacity in Diabetic patients with lower limb amputation surgery. Design and criteria: This study is prospective, randomized and clinical trial. In this study were randomly divided into three groups. In group 1, with general anesthesia (n = 20), pretreatment with midazolam 0.4 mg/kg, fentanyl 3 micrograms per kilogram, and the induction of anesthesia with propofol 2 mg/kg, were used. In group 2 (n=20) with spinal anesthesia, 3 ml Bupivacaine 0.5% was injected into the subarachnoid space of the spinal canal between the third and fourth lumbar space or between the fifth lumbar and first sacral space of the spinal column. In third group with 23 healthy volunteers (age and gender-matched) were recruited to have a control group for a better interpretation of laboratory data in our patients. Inclusion criteria: Diabetic patient with diabetic foot who were candidate for lower limb amputation. Exclusion criteria: Lack of consent to participate in the study; Antioxidant supplements such as vitamin C; Neuraxial uplink block is prohibited; End-stage renal disease. Primary outcome: Serum total antioxidant capacity and Level of Serum Lipid Peroxidation. Time of measurement: Before induction, 1 hour after surgery. Intervention group: group 1 and 2 candidates for amputation under general and spinal anesthesia. Control group: 23 healthy volunteers were recruited to have a control group for a better interpretation of laboratory data in our patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402208384N3**
Registration date: **2014-08-01, 1393/05/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-01, 1393/05/10

Registrant information

Name

Arash Peivandi Yazdi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1852 5209

Email address

peivandia@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Science

Expected recruitment start date

2012-11-30, 1391/09/10

Expected recruitment end date

2013-08-01, 1392/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Spinal and General Anesthesia on Serum Lipid Peroxides and Total

Antioxidant Capacity in Diabetic Patients with Lower Limb Amputation Surgery

Public title

Comparison of general and spinal anesthesia on the body's defense systems in diabetic patients

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Diabetic patient with diabetic foot who were candidate for lower limb amputation. Exclusion criteria: Lack of consent to participate in the study; Antioxidant supplements such as vitamin C; Neuraxial uplink block is prohibited; End-stage renal disease.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 63

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

Ethics Committee of Mashhad University of Medical sciences

Street address

Ghoreishi apartment, Daneshgah street, Mashhad

City

Mashhad

Postal code

Approval date

2012-11-21, 1391/09/01

Ethics committee reference number

910198

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Serum total antioxidant capacity

Timepoint

Before induction, 1 hour after surgery

Method of measurement

Antioxidant Assay Kit

2

Description

Level of Serum Lipid Peroxidation

Timepoint

Before induction, 1 hour after surgery

Method of measurement

TBARS (Thiobarbitoric Acid Reactive Substances Assay kit)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 : In group 1 with general anesthesia (n = 20), pretreatment with midazolam 0.4/0 mg kg, fentanyl 3 micrograms per kilogram, and the induction of anesthesia with propofol 2 mg kg, were used

Category

Treatment - Drugs

2

Description

Intervention group 2 : For patients in SA group, 3 ml Bupivacaine 0.5% was injected into the subarachnoid space of the spinal canal between the third and fourth lumbar space or between the fifth lumbar and first sacral space of the spinal column

Category

Treatment - Drugs

3

Description

Control group: 23 healthy volunteers (age and gender-matched) were recruited to have a control group for a better interpretation of laboratory data in our patients.

Category

N/A

Department of Anesthesia, Imam Reza Hospital, Ibne Sina Street, Mashhad

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person

Dr Arash Peivandi

Street address

Imam Reza Hospital, Ibne Sina street, Mashhad

City

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Mashhad University of Medical Science

Full name of responsible person

Mohsen Tafaghodi

Street address

Ghoreishi apartment, Daneshgah street, Mashhad,

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Mashhad

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, Mashhad University of Medical Science

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****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Arash Peivandi Yazdi

Position

Assistant professor

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Web page address

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