Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of frequency and severity of intraoperative hypothermia between general anesthesia and spinal anesthesia in patients with lower extremity procedures

Protocol summary

Summary

This study aimed to compare the incidence and severity of hypothermia for general anesthesia and spinal anesthesia in the lower extremities is a randomized clinical trial in 60 patients undergoing lower extremity that Imam Reza (AS) visited. Patients are randomly divided in two equal groups of 30 each. Patients with ASA I, II are included and in condition that the ASA> II; addiction; blood coagulation disorders and infections patients are excluded. The first group received spinal anesthesia space L3-L4 or L4 - L5 injection of Marcaine solution (0.5%) 12-15 mg plus fentanyl 25µ. If more than 30mmHg hypotension occurs, 5-10 mg ephedrine is injected. The second group underwent induction of anesthesia with propofol (2ml/kg) and Atracurium (0.5 ml/kg) are placed. After intubation, anesthesia with propofol (100µ/kg/min) oxygen and 50% nitrous oxide and fentanyl 50µ every half hour is used as a preservative. Symptoms hemodynamic (heart rate, systolic and diastolic), oxygen saturation, temperature, forehead and tympanic beginning of anesthesia and then every 30 minutes until the end of surgery and transferred to the recovery room monitors are. Patients under general anesthesia after surgery, patients undergoing spinal anesthesia during surgery and recovery and transfer are assessed for shivering.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042917480N1**
Registration date: **2014-05-21, 1393/02/31**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-05-21, 1393/02/31

Registrant information

Name
Mostafa Delshad
Name of organization / entity
Mashhad University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 51 1606 6269
Email address
delshadm1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of frequency and severity of intraoperative hypothermia between general anesthesia and spinal anesthesia in patients with lower extremity procedures

Public title

Evaluation of heat loss during anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patients undergoing lower extremity; new ASA I, II; consent to participate in the study. Exclusion: ASA> II; a lack of consent to spinal anesthesia; any prohibitive (in terms of anesthesia and surgery) for spinal anesthesia, drugs, blood coagulation disorders, infections, spinal area; patients who have contraindications to general anesthesia.

Age
From **1 year** old to **13 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad University of Medical Sciences

Street address
Ghoreyshi Building, Daneshgah Street

City
Mashhad

Postal code

Approval date
2014-04-26, 1393/02/06

Ethics committee reference number
922148

Health conditions studied

1

Description of health condition studied
Hypothermia during and after surgery

ICD-10 code
T88.5

ICD-10 code description
Other complications of anaesthesia

Primary outcomes

1

Description
Hypothermia

Timepoint
Ambient temperature, the top of the forehead and tympanic membrane anesthesia and then every 30 minutes until the end of the surgery and the recovery

Method of measurement
digital thermometer (beurer) Model FT55

Secondary outcomes

1

Description
Duration of surgery

Timepoint
Duration of anesthesia and patient recovery

Method of measurement
Minute

Intervention groups

1

Description
The first group received spinal anesthesia space L3-L4 or L4 - L5 injection of Marcaine solution (0.5%) 12-15 mg plus fentanyl 25µ are.More than 30mmHg hypotension occurs, the patient is injected mg10 - 5 ephedrine are treated.

Category
Treatment - Other

2

Description
The second group underwent induction of anesthesia with propofol (2ml/kg) and Atracurium (0.5 ml/kg) are placed. After intubation, anesthesia with propofol (100µ/kg/min) oxygen and 50% nitrous oxide and fentanyl 50µ every half hour is used as a preservative.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Cardiac Anesthesia Research Center

Full name of responsible person
Dr. Mehryar Taghavi Gilani

Street address
Cardiac Anesthesia Research Center, Imam Reza Hospital, Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran

City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Vice Chancellor for Research, Ghoreyshi Building, Daneshgah Street
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mehryar Taghavi Gilani
Position
Associate Professor
Other areas of specialty/work
Street address
Cardiac Anesthesia Research Center, Imam Reza Hospital, Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran
City
Mashhad
Postal code
Phone
+98 51 1852 5209
Fax
Email
taghavim@mums.ac.ir
Web page address
http://www.mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mehryar Taghavi Gilani
Position
Associate Professor of Anesthesiology
Other areas of specialty/work
Street address
Cardiac Anesthesia Research Center, Imam Reza Hospital, Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran
City
Mashhad
Postal code
Phone
+98 51 1852 5209
Fax
Email
taghavim@mums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mostafa Delshad
Position
Resident of Anesthesiology
Other areas of specialty/work
Street address
Cardiac Anesthesia Research Center, Imam Reza Hospital, Faculty of Medicine, Mashhad University of Medical Sciences, Mashhad, Iran
City
Mashhad
Postal code
Phone
+98 51 1606 6269
Fax
Email
delshadm1@mums.ac.ir
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