Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of Phenylephrine and Ephedrine in the treatment of hypotension after spinal anesthesia

Protocol summary

Summary

Abstract: Phenylephrine and Ephedrine for spinal anesthesia induced hypotention after elective orthopedic surgeries Background One of the most common complications of spinal anesthesia is hypotention, so there is no general agreement on the treatment of this event. The aim of this study is assessing and comparing of Phenylephrine and Ephedrine on treatment of hypotention after spinal anesthesia in orthopedic surgeries in Alzahra University Hospital in Isfahan in 2015. Materials and Methods In this double-blind clinical trial 110 patients undergoing elective orthopedic surgeries will be randomized into two groups. Patients receive 50µg Phenylephrine(group P), and 5mg ephedrine(group E); both intravenously after observation of hypotension episode. We compare hemodynamic parameters (blood pressure, heart rate) and the incidence of hypotension and other complications and also total dose of vasoconstrictor used in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015070920588N3**
Registration date: **2015-11-12, 1394/08/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-11-12, 1394/08/21

Registrant information

Name

Darioush Moradi Farsani

Name of organization / entity

Isfahan Univesity of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research deputy of Isfahan University of Medical Scienses

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Phenylephrine and Ephedrine in the treatment of hypotension after spinal anesthesia

Public title

Comparison of Phenylephrine and Ephedrine in the treatment of hypotension

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: 110 patient with ASA physical status class I-II aged 40-65 years who are candidates of lower extremity orthopedic surgery. Exclusion criteria:Any hypersensitivity reaction to vasopressore or local anesthetic drugs, systemic diseases like cardiovascular, liver, or renal diseases and pregnancy.

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

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

Isfahan University of Medical Sciences

Street address

Research Deputy, Isfahan university of medical sciences, Hezarjrib Street, Isfahan, Iran

City

Isfahan

Postal code

Approval date

2014-12-11, 1393/09/20

Ethics committee reference number

13625 /8/د

Health conditions studied

1

Description of health condition studied

Hypotension

ICD-10 code

195.2

ICD-10 code description

Hypotension due to drugs

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

2, 4, 6, 8, 10, 14, 20 and 30 minutes after arrival of the patient to the recovery room.

Method of measurement

Noninvasive Blood pressure monitoring system

2

Description

Diastolic blood pressure

Timepoint

2, 4, 6, 8, 10, 14, 20 and 30 minutes after arrival of the patient to the recovery room.

Method of measurement

Noninvasive Blood pressure monitoring system

3

Description

Mean arterial blood pressure

Timepoint

2, 4, 6, 8, 10, 14, 20 and 30 minutes after arrival of the patient to the recovery room.

Method of measurement

Noninvasive Blood pressure monitoring system

Secondary outcomes

1

Description

Heart rate

Timepoint

2 ،4 ، 6 ، 8 ، 10 ، 14 ، 20 and 30 minutes after arrival of the patient to the recovery room

Method of measurement

pulse oxymetery

2

Description

Arterial blood oxygen saturation

Timepoint

2 ،4 ، 6 ، 8 ، 10 ، 14 ، 20 and 30 minutes after arrival of the patient to the recovery room

Method of measurement

pulse oxymetery

3

Description

Drug and non drug related complications

Timepoint

Any time during the study

Method of measurement

clinical evaluation

Intervention groups

1

Description

Intervention group-1 :Will receive 50µg

Phenylephrine(group P) intravenously after observation of hypotension episode(grater than %20 of baseline blood pressure) and in non responsive cases ephedrine will be infused and repeated till achieving normal blood pressure. If bradycardia develops (Heart rate bellow 60 beat per minute) 0.5 mg Atropine IV will be infused.

Category

Treatment - Drugs

2

Description

Intervention group-2 :Will receive 5mg Ephedrine(group E) intravenously after observation of hypotension episode(grater than %20 of baseline blood pressure) and in non responsive cases ephedrine will be infused and repeated till achieving normal blood pressure. If bradycardia develops (Heart rate bellow 60 beat per minute) 0.5 mg Atropine IV will be infused.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Feiz University Hospital

Full name of responsible person

Dr Darioush Moradi Farsani

Street address

Feiz University Hospital, Soroush Street, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vce chancellor for research of Isfahan University of Medical Scienses

Full name of responsible person

dr Mehdi Nematbakhsh

Street address

Research daeputy, Isfahan University of Medical Sciences, Hezargrib Street, Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vce chancellor for research of Isfahan University of Medical Scienses

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

Isfahan University of Medical Sciences

Full name of responsible person

Darioush Moradi

Position

Assistant Professor of Anesthesia and Critical care

Other areas of specialty/work

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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