# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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

**Country**

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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

**City**

Isfahan

## 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**

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Isfahan University of Medical Sciences

**Full name of responsible person**

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**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*