

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of Phenylephrine and Ephedrine in treatment of Hypotension during Spinal Anesthesia for Cesarean Section

#### Protocol summary

##### Summary

Aim: comparing the effect of Phenylephrine and ephedrine in the treatment of hypotension caused by nerve block in the spinal anesthesia in patient undergoing cesarean section in Dezyany educational and medical center, Gorgan, Iran, 2012. It is a double-blind, clinical trial with inclusion criteria: patients older than 18 yr., ASA (American Society of Anesthesiologists) I and II and exclusion criteria: women with pre-existing or pregnancy-induced hypertension. 104 patients who were undergoing cesarean section were randomized into two groups: Group P (100µg Phenylephrine) and Group E (6µg Ephedrine). We compared the hemodynamic parameters (blood pressure, heart rate) and the incidence of hypotension between the two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012072910340N4**

Registration date: **2012-08-15, 1391/05/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-08-15, 1391/05/25

##### Registrant information

###### Name

Mohammad Aryaie

###### Name of organization / entity

Golestan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 911 277 1798

##### Email address

aryaie@goums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Golestan university of medical sciences

##### Expected recruitment start date

2011-07-14, 1390/04/23

##### Expected recruitment end date

2012-04-22, 1391/02/03

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Phenylephrine and Ephedrine in treatment of Hypotension during Spinal Anesthesia for Cesarean Section

##### Public title

Comparison of phenylephrine and ephedrine for Hypotension treatment

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients older than 18 yr.; ASA (American Society of Anesthesiologists) I and II; weight of 50–120 kg; height of 150–180 cm; women with singleton pregnancies scheduled for elective caesarean delivery under spinal anesthesia. Exclusion criteria: Women with pre-existing or pregnancy-induced hypertension, diabetes mellitus, known cardiovascular or cerebrovascular disease, fetal abnormality, or contraindication to spinal anesthesia.

##### Age

From **15 years** old to **50 years** old

##### Gender

Female

### Phase

2-3

### Groups that have been masked

No information

### Sample size

Target sample size: **104**

### 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

Golstan university of medical sciences

##### Street address

Golestan university of medical sciences

##### City

Gorgan

##### Postal code

#### Approval date

2010-08-20, 1389/05/29

#### Ethics committee reference number

90010025157

## Health conditions studied

### 1

#### Description of health condition studied

hypotension

#### ICD-10 code

E00-E90

#### ICD-10 code description

Endocrine, nutritional and metabolic diseases

## Primary outcomes

### 1

#### Description

hypotension

#### Timepoint

during surgery

#### Method of measurement

monitoring

## Secondary outcomes

### 1

#### Description

nausea and vomiting

#### Timepoint

after general anesthesia in recovery

#### Method of measurement

ask from patient

## Intervention groups

### 1

#### Description

Group E received a 1-mL bolus of ephedrine 6 mg/mL

#### Category

Treatment - Drugs

### 2

#### Description

Group P received a 1-mL bolus of phenylephrine 100 µg/mL

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dezyani hospital

##### Full name of responsible person

##### Street address

##### City

Gorgan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Golestan University of medical sciences

##### Full name of responsible person

Dr. Mohammad Vakili (Director of Research and Technology)

##### Street address

Vice chancellor for Research, Golestan University of Medical Sciences, kilometer 2 of Sari road

##### City

Gorgan

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Golestan 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**  
5th of Azar hospital  
**Full name of responsible person**  
Kazem Kazem nejad  
**Position**  
anesthesiologist  
**Other areas of specialty/work**  
**Street address**  
5th of Aar hospital, Kkh squire, 5 Azar street  
**City**  
Gorgan  
**Postal code**  
**Phone**  
+98 17 1442 1651  
**Fax**  
**Email**  
kazemnejad1341@yahoo.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Golestan university of medical sciences  
**Full name of responsible person**  
Mohammad Aryaie  
**Position**  
master  
**Other areas of specialty/work**  
**Street address**

5th of Azar hospital  
**City**  
Gorgan  
**Postal code**  
**Phone**  
+98 17 1442 1651  
**Fax**  
**Email**  
aryaie2009@yahoo.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Golestan university of medical sciences  
**Full name of responsible person**  
Amin hasanzad  
**Position**  
bachelor degree  
**Other areas of specialty/work**  
**Street address**  
5th Azar hospital  
**City**  
Gorgan  
**Postal code**  
**Phone**  
**Fax**  
**Email**  
hassanzad\_amin@yahoo.com  
**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*