

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### The effects of Phenylephrine & Ephedrine on maternal hemodynamic changes and umbilical cord arterial blood gases in spinal anesthesia

#### Protocol summary

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#### Summary

The aim of study is evaluating the prophylactic effect of phenylephrine and ephedrine in hemodynamic state of elective cesarean cases during spinal anesthesia. 100 pregnant women with age 18-35 years was studied. After establishing vital sign and spinal anesthesia with 12mg Bupivacaine 0.5%, slow injection of a prophylactic dose of 100 microgram phenylephrine or 10 mg ephedrine was administered intravenously to patients randomly. Blood pressure and heart rates, nausea & vomiting in mothers and infants apgar score in 1 and 5 minutes of schedule in the chart of each patient was recorded. Arterial blood samples were taken from the infant's umbilical cord.

#### Recruitment status

**Recruitment complete**

#### Funding source

vice-chancellor Of Research Babol University Of Medical Sciences

#### Expected recruitment start date

2012-05-30, 1391/03/10

#### Expected recruitment end date

2012-09-20, 1391/06/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT201208136148N2**

Registration date: **2013-01-25, 1391/11/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2013-01-25, 1391/11/06

#### Registrant information

#### Name

Hakimeh Alreza Amiri

#### Name of organization / entity

Babol University of Medical Sciences

#### Country

Iran (Islamic Republic of)

#### Phone

+98 11 1223 8296

#### Email address

#### Scientific title

The effects of Phenylephrine & Ephedrine on maternal hemodynamic changes and umbilical cord arterial blood gases in spinal anesthesia

#### Public title

The effects of Phenylephrine and Ephedrine on maternal blood pressure and heart rate variation and umbilical cord arterial blood gases in spinal anesthesia

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: 18 to 35 years pregnant women candided for cesarean section with ASA class I, II Exclusion criteria: Hypertension BP > 140/90; DM; Cardiovascular and cerebrovascular disease; Significant fetal abnormalities; contraindication of spinal anesthesia; mothers who are at the start of active phase of labor

#### Age

From **18 years** old to **35 years** old

#### Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Babol University of Medical Sciences

##### Street address

Daneshgah Squire, Ganjafrooz Avenue

##### City

Babol

##### Postal code

#### Approval date

2012-05-26, 1391/03/06

#### Ethics committee reference number

6432/30/ز/پ

## Health conditions studied

### 1

#### Description of health condition studied

Cesarean Section

#### ICD-10 code

O74

#### ICD-10 code description

Complications of anaesthesia during labour and delivery

## Primary outcomes

### 1

#### Description

Blood pressure

#### Timepoint

Baseline BP before Spinal anesthesia and every 2 minutes control until the end of surgery

#### Method of measurement

Non invasive BP Cuff

### 2

#### Description

Heart rate

#### Timepoint

Before spinal anesthesia until the end of surgery every 2 minutes

#### Method of measurement

ECG

## Secondary outcomes

### 1

#### Description

Lactate of umbilical artery

#### Timepoint

Immediatly after birth

#### Method of measurement

ABG

### 2

#### Description

Infant Apgar

#### Timepoint

1 and 5 minutes after birth

#### Method of measurement

Apgar Score

### 3

#### Description

Nausea & Vomiting

#### Timepoint

During spinal anesthesia

#### Method of measurement

Observation

### 4

#### Description

PH of umbilical artery

#### Timepoint

Immediatly after birth

#### Method of measurement

ABG

### 5

#### Description

Base excess

#### Timepoint

Immediatly after birth

#### Method of measurement

ABG

## Intervention groups

### 1

#### Description

100 microgram phenylephrine IV injection in one minute

after spinal anesthesia to first group

**Category**

Prevention

**2**

**Description**

10mg ephedrine IV prophylactic injection in one minute after spinal anesthesia to second group

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ayatollah Ruhani Hospital

**Full name of responsible person**

**Street address**

**City**

Babol

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice-chancellor Of Research Babol University Of Medical Sciences

**Full name of responsible person**

Dr Amrolah Mostafazadeh

**Street address**

Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

**City**

Babol

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice-chancellor Of Research Babol 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**

Babol University Of Medical Sciences

**Full name of responsible person**

Dr Hakimeh Alereza Amiri

**Position**

Assistant Professor Of Anesthesiology

**Other areas of specialty/work**

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Dr Hakimeh Alereza Amiri

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**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Statistical Analysis Plan**

**Data Dictionary**

*empty*