

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effect of Prophylactic Infusion of Ephedrine and Phenylephrine Combination on Maternal Hemodynamics after Spinal Anesthesia for Cesarean section

#### Protocol summary

##### Summary

Hypotension, a frequent complication of spinal anesthesia for caesarean delivery, can have adverse maternal and fetal effects. Single-agent prophylaxis, most notably with ephedrine, does not reliably prevent spinal anesthesia-induced hypotension. The aim of this study is evaluate the effect of prophylactic infusion of ephedrine and phenylephrine combination on maternal hemodynamics after spinal anesthesia for cesarean section. In this double-blind, randomized, and placebo-controlled clinical trial, 90 parturients undergoing spinal anesthesia for elective cesarean delivery were randomized to receive an prophylactic IV infusion of phenylephrine and ephedrine combined in the study group (n=45) or normal saline in the placebo group (n=45) from 15 minutes before the start of spinal block. The infusions are adjusted to maintain systolic blood pressure (SBP) near baseline until induction of anesthesia. Hemodynamic changes, total consumption of vasoconstrictors, and umbilical cord blood gases are compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201401277013N6**  
Registration date: **2014-02-10, 1392/11/21**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-02-10, 1392/11/21

##### Registrant information

Name

Simin Atashkhoei

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3333 3806

##### Email address

atashkhoei@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2013-11-03, 1392/08/12

##### Expected recruitment end date

2014-08-02, 1393/05/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Prophylactic Infusion of Ephedrine and Phenylephrine Combination on Maternal Hemodynamics after Spinal Anesthesia for Cesarean section

##### Public title

Effect of prophylactic of ephedrine and phenylephrine combination in control of maternal hypotension after spinal anesthesia for cesarean section

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: term pregnancy; aged 18-40 years;

ASA class I or II; scheduled for Cesarean section; scheduled for spinal anesthesia. Exclusion criteria: contraindication for spinal anesthesia; allergy to local anesthetics; Organic dysfunction (cardiovascular; cardiovascular disease,...) fetal abnormalities; maternal hypertension; chronic medication abuse

#### Age

From **18 years** old to **40 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **90**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Vice Chancellor of Tabriz University of Medical Sciences

##### Street address

Research Vice Chancellor; Tabriz University; Daneshgah Street; Tabriz

##### City

Tabriz

##### Postal code

#### Approval date

2013-11-03, 1392/08/12

#### Ethics committee reference number

92115

## Health conditions studied

### 1

#### Description of health condition studied

Hypotension after spinal anesthesia

#### ICD-10 code

I95.2

#### ICD-10 code description

Hypotension due to drugs

## Primary outcomes

### 1

#### Description

Blood pressure

#### Timepoint

Baseline and every 2 minutes after start of study solution infusion

#### Method of measurement

mmHg

## Secondary outcomes

### 1

#### Description

Total dose of vasoconstrictors

#### Timepoint

After spinal anesthesia to end of operation

#### Method of measurement

Doses of medications by mg or ug

## Intervention groups

### 1

#### Description

In the study group(n=45) ephedrine 10mg plus phenylephrine 125 ug into 15 ml normal saline at rate of 60 ml/h (within 15 min) is infused.

#### Category

Prevention

### 2

#### Description

In the placebo group(n=45) 15 ml normal saline at rate of 60 ml/h (within 15 min) is infused.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Al-Zahra Hospital

##### Full name of responsible person

Dr.Simin Atashkhooi

##### Street address

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Vice Chancellor for Research, Tabriz University of  
Medical Sciences

**Full name of responsible person**

Dr. Rashidi

**Street address**

Research Vice Chancellor; Daneshgah Street; Tabriz

**City**

TABRIZ

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for Research, Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Simin Atashkhoyi

**Position**

Anesthesiologist/ Professor

**Other areas of specialty/work**

**Street address**

Al-Zahra Hospital; South Artesh street; Tabriz

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1553 9161

**Fax**

**Email**

satashkhoyi@gmail.comsiminatashkhoyii@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Simin Atashkhoyi

**Position**

Anesthesiologist/Professor

**Other areas of specialty/work**

**Street address**

Al-Zahra Hospital; South Artesh street; Tabriz

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1553 9161

**Fax**

**Email**

satashkhoyi@gmail.comsiminatashkhoyii@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Simin Atashkhoyi

**Position**

Anesthesiologist/Professor

**Other areas of specialty/work**

**Street address**

Al-Zahra Hospital; South Artesh street; Tabriz

**City**

**Postal code**

**Phone**

00

**Fax**

**Email**

**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*