

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

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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 Atashkhooii

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

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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