Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of prophylactic infusion of phenylephrine with ephedrine for prevention of hypotension in elective cesarean section under spinal Anesthesia

Protocol summary

Summary

Abstract Aims: Spinal anesthesia is an accepted technique of anesthesia in elective cesarean sections. However hypotension, resulted from sympathectomy is a common problem especially in pregnant women and prevention of this complication by sysmpathomimetic agents is of potential clinical significance. The aim of this study is to compare the effect of prophylactic infusion of Phenylephrine versus Ephedrine in prevention of hypotension during spinal anesthesia in elective cesarean section. Design: This study is a randomized double- blind clinical trial which is performed on 90 patients in Tabriz Alzahra obstetric hospital during approximately 17 months. Methods: Ninety patients are enrolled in this study and are divided randomly to three groups to receive intervention drugs or placebo. After completion of infusions, all patients were received spinal anesthesia, in sitting position from L4-L5 or L3-L4 inter vertebral spaces with 2.5cc of Bupivacaine 0.5%(12.5mg) and 2.5 µg sufentanil. Participants' of the study are healthy pregnant women with gestational age of 36 weeks or higher who are candidate for elective cesarean section under spinal anesthesia. Patients with <36 weeks of gestation , emergency cesarean section, high risk, any contraindication of spinal anesthesia and unexpected events during surgery are excluded from study. Interventions: Ninety patients are enrolled in this study and are divided randomly to three groups. Group Ph received phenylephrine infusion, group E received ephedrine infusion while group P were delivered placebo. Basic variables of outcome: perioperative maternal vital signs (Blood pressure, heart rate and arterial oxygen saturation) and Maternal perioperative complications and also neonatal outcome including 1st and 5th apgar scores and arterial blood gas analyses are recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012120911700N1**
Registration date: **2013-07-21, 1392/04/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-07-21, 1392/04/30

Registrant information

Name

Farnaz Moslemi Tabrizi

Name of organization / entity

Alzahra hospital, Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

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moslemif@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Women's Reproductive Health Research Center, Tabriz University of Medical Sciences, Tabriz, Iran

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2013-08-22, 1392/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of prophylactic infusion of phenylephrine with ephedrine for prevention of hypotension in elective cesarean section under spinal Anesthesia

Public title
Prophylactic effect of phenylephrine on post-spinal hypotension during cesarean section

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criterion: any healthy pregnant women with gestational age of 36 weeks or higher and non emergency cesarean section. Exclusion criteria: gestational age less than 36 weeks; emergency cesarean section; any contraindication of spinal anesthesia (patient refusal , coagulopathy , hemorrhage or hypovolemic shock) and unexpected events during surgery such a hemorrhage or sensory block level blow or higher then T4-T5 after spinal anesthesia.

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
Women's Reproductive Health Research Center,Tabriz University of Medical Sciences, Tabriz, Iran

Street address
Tabriz Univercity of Medical Sciences, Daneshgah ave, Tabriz

City
Tabriz

Postal code

Approval date
2008-11-24, 1387/09/04

Ethics committee reference number
5/4/3036

Health conditions studied

1

Description of health condition studied
Spinal Anesthesia, Hypotention

ICD-10 code
O89.5

ICD-10 code description
Other complications of spinal and epidural anaesthesia during the puerperium

Primary outcomes

1

Description
Blood pressure

Timepoint
Every 5 minute until fetal delivery,then every 5 minute throughout surgery

Method of measurement
Noninvasive blood pressure control with noninvasive mamometer

2

Description
Maternal complications(Dysrhythmias,nausea and vomiting,other complications) ting,other complications

Timepoint
Continuous Inspection

Method of measurement
Electrocardiogram, continuous Inspection

Secondary outcomes

1

Description
Neonatal outcome

Timepoint
1st and 5th minutes Apgar Scores after neonatal delivery

Method of measurement
1st and 5th minutes Apgar Scoring system

Intervention groups

1

Description
Intervention group1: Infusion of 450 micrograms Phenylephrine in 250 milliliters of normal saline during 30 minutes before performing spinal anesthesia

Category

Treatment - Drugs

2

Description
Intervention group 2: Infusion of 45 milligrams Ephedrine in 250 milliliters of normal saline during 30 minutes before performing spinal anesthesia
Category
Treatment - Drugs

3

Description
Control group::Infusion of 250 milliliters of normal saline during 30 minutes before performing spinal anesthesia
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra academic hospital
Full name of responsible person
Farnaz Moslemi Tabrizi
Street address
South Artesh Ave.Alzahra academic hospital
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sceince
Full name of responsible person
Dr. Alireza Ostad Rahimi
Street address
Golgasht ave, Daneshgah square, 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 Sceince
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
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Anesthesiologist,Associated professor of Anesthesia
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Person responsible for updating data

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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