Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of Intravenous Phenylephrine and Ephedrine to Treat Hypotension Associated with Spinal Anesthesia in Patients Undergoing Cesarean Section

Protocol summary

Summary

The purpose of this study is the comparison of intravenous Phenylephrin and Ephedrin to treat hypotension associated with spinal anesthesia in the patients undergoing cesarean section. The study was placed in Ali- ebn- Abitaleb hospital operating room in Zahedan, 2015. A double-blind clinical trial was carried out on 120 patients. Inclusion and exclusion criteria are as follows: Inclusion criteria: 20-35 years old, Elective surgery, ASA class 1, pregnancy, Gestational age 30-36 week. Exclusion criteria : History of primary HTN, cardio-cerebro vascular diseases, Diabetic mellitus, malformation of placenta and umbilical cord, high risk pregnancy, Gestational HTN, Contraindication of spinal Anesthesia. Exclusion criteria during the study: abnormal hemorrhage under surgery, unsuccessful spinal anesthesia, high spinal Anesthesia (at level above T4), more than 75min surgery duration. In the present study, the patients were divided into 4 categories randomly, each including 30 patients. At the first, the patients were received Ringer located 10 cc/kg and then spinal Anesthesia was performed with Bupivacain and Fentanyl. When Hypotension was occurred Ephedrin or Phenylephrine was given as follows: in the first category Ephedrin 5mg, in the second category Ephedrin 10mg, in the third category Phenylephrine 50µg, in the fourth category Phenylephrine 100µg Bolous, and also they would received repeated Bolous duos if needed. During spinal anesthesia, BP and HR were checked for 75 minutes (every 3 minutes for the first 15-minute period and every 10 minutes for the following 60-minute period). Also nausea and vomiting were recorded during the surgery. Acid-base status was investigated for arterial umbilical cord blood after the extraction of fetus and umbilical cord clamp. Also neonatal Apgar was checked at 1 and 5 minutes after birth.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050622131N1**
Registration date: **2015-09-19, 1394/06/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-09-19, 1394/06/28

Registrant information

Name

Hedayatollah Vakili

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 917 101 6247

Email address

vakili_h@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Zahedan University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of Intravenous Phenylephrine and Ephedrine to Treat Hypotension Associated with Spinal Anesthesia in Patients Undergoing Cesarean Section

Public title
Comparison of Intravenous Phenylephrine and Ephedrine to Treat Hypotension Associated with Spinal Anesthesia in Patients Undergoing Cesarean Section

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:Pregnant women 2o-35 years old ;Elective cesarean;ASA1; Singleton pregnancy;36 to 40 weeks gestational age;Weighing 45 to 90 kg;145 to 180 cm height;Informed consent for inclusion Exclusion criteria beginning: History of Primary hypertension (Bp≥140/90);cardio-cerebrovascular diseases; Diabetic mellitus;Sensitivity to anesthetics;Pregnancy complications such as gestational hypertension;Placental abnormalities;Umbilical cord abnormalities;High-risk pregnancies(Multiple pregnancy،Intrauterine growth retardation);Spinal anesthesia ban(Prevention of spinal anesthesia،Coagulation disorder،Infection of spinal anesthesia area);Lack of consent to participate in the study Exclusion criteria during the study:Unpredictable events during surgery such as abnormal hemorrhage under surgery; unsuccessful spinal anesthesia;high spinal Anesthesia (at level above T4); more than 75min surgery duration

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **120**

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
Zahedan University of Medical Sciences

Street address
Zahedan Medical Sciences University campus office complex,Khalij e Fars Avenue,Dr.Hesabi Square,Zahedan.Iran

City
zahedan

Postal code
98167-43463

Approval date
2015-06-14, 1394/03/24

Ethics committee reference number
IR.ZAUMS.REC.1394.130

Health conditions studied

1

Description of health condition studied
Maternal hypotension

ICD-10 code
o26.5

ICD-10 code description
Maternal hypotension syndrome

Primary outcomes

1

Description
Blood pressure

Timepoint
After spinal anesthesia,75 minutes (every 3 minutes for the first 15-minute period and every 10 minutes for the following 60-minute period

Method of measurement
mmHg by SIEMENS SC 7000 monitoring system

2

Description
Heart rate

Timepoint
After spinal anesthesia, were checked for 75 minutes (every 3 minutes for the first 15-minute period and every 10 minutes for the following 60-minute period

Method of measurement
Number by SIEMENS SC 7000 Monitoring system

Secondary outcomes

1

Description
Base Exess

Timepoint
After the extraction of fetus and umbilical cord clamp

Method of measurement

Number -Based on the arterial umbilical cord Base Exess,that was measured by blood gas analyzer ,GASTAT-603ie

2

Description
Nausea
Timepoint
During Surgery
Method of measurement
Has/has not,Patient-reported

3

Description
Vomiting
Timepoint
During Surgery
Method of measurement
Has/has not,Observer-reported

4

Description
Umbilical cord Ph
Timepoint
After the extraction of fetus and umbilical cord clamp
Method of measurement
Number -Based on the arterial umbilical cord PH,that was measured by blood gas analyzer ,GASTAT-603ie

5

Description
Neonatal Apgar
Timepoint
At 1 and 5 minutes after birth.
Method of measurement
Based on clinical examination

Intervention groups

1

Description
Bolus injection of 5 mg ephedrine if hypotension is more than 20% from baseline and If necessary, repeat dose, 5 mg
Category
Treatment - Drugs

2

Description
Bolus injection of 10 mg ephedrine if hypotension is more than 20% from baseline and If necessary, repeat dose,10 mg
Category
Treatment - Drugs

3

Description
Bolus injection of 50µg phenylephrine if hypotension is more than 20% from baseline and If necessary, repeat dose, 50µg
Category
Treatment - Drugs

4

Description
Bolus injection of 100 µg phenylephrine if hypotension is more than 20% from baseline and If necessary, repeat dose, 100 µg
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali- ebn- Abitaleb hospital operating room in Zahedan
Full name of responsible person
Hedayatollah Vakili
Street address
Zahedan ,Ali- ebn- Abitaleb hospital operating room
City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor Of Research Zahedan University Of Medical Sciences
Full name of responsible person
Houshang Rafighdoost
Street address
Zahedan Medical Sciences University campus office complex,Khalij e Fars Avenue,Dr.Hesabi Square,Zahedan.Iran
City
Zahedan
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 Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Hedayatollah Vakili
Position
Anesthesia Assistant
Other areas of specialty/work
Street address
Ali- ebn- Abitaleb hospital operating room in Zahedan
City
Zahedan
Postal code
9816883883
Phone
+98 71 3843 8875
Fax
Email
vakili_h@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Hassan Enayati
Position
Assistant Professor Of Anesthesia
Other areas of specialty/work
Street address
Ali- ebn- Abitaleb hospital operating room in Zahedan
City
Zahedan
Postal code
Phone
+98 54 3322 3001
Fax
Email
enayati_hassan@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Hedayatollah Vakili
Position
Anesthesia Assistant
Other areas of specialty/work
Street address
Ali- ebn- Abitaleb hospital operating room in Zahedan
City
Zahedan
Postal code
9816883883
Phone
+98 71 3843 8875
Fax
Email
vakili_h@sums.ac.ir
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