Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Summary

The aim of study is evaluating the prophylactic effect of phenylepherine and ephedrine in hemodynamic state of elective cesarean cases during spinal anesthesia. 100 pregnant women with age 18-35 years was studied.After stablishing 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.

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

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Name of organization / entity

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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

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 Phenylepherine and Ephedirne 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 secton with ASA class I,II Exclusion criteria: Hypertension BP>140/90; DM; Cardiovascular and cerbrovascular 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 Squre, Ganjafrooz Avenue
City
Babol
Postal code
Approval date
2012-05-26, 1391/03/06
Ethics committee reference number
6432/30/ژ/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 phenylepherine 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

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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

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Full name of responsible person

Dr Hakimeh Alereza Amiri

Position

Assistant Professor Of Anesthesiology

Other areas of specialty/work

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City

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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