Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Comparison between different prophylactic & therapeutic phenylephrine regimenes in reducing maternal hypotention after induction of spinal anesthesia in caesarean section

Protocol summary

Summary

1)Objectives: hypotension remains the most common complication of spinal anesthesia in cesarean section. A lot of studies have been performed to solve this problem but there are still controversies. This investigation was planned to find the best dose and the best way of phenylephrine administration to reduce the incidence of spinal anesthesia induced hypotension in cesarean section. 2) Design: 120 patients will be studied in 3 groups. Groups 1 & 2 will receive prophylactic 100 microgram bolus dose or 50 µg /min infusion of phenylephrine immediately after spinal anesthesia and the third group (placebo) will receive normal saline. 3) Setting & conduct:all of the drugs will be prepared in the same syringes with the same volume. The patient and the nurse who recorded the vital signs are not aware of the grouping. Patient's blood pressure will be measured by non invasive blood pressure monitoring and will be recorded. In the case of hypotension which was defined as more than 20% decline in blood pressure compared to baseline, 100 µg phenylephrine in one ml volume will be injected in all three groups and if hypertension was detected, the infusing solution will be hold. 4): Participants including major eligibility criteria: all of the ASA 1 healthy term parturients referring to Fatemieh hospital candidate for Cesarean section will be included in the study. Exclusion criteria: chronic hypertension; preeclampsia; twin pregnancy;, preterm labor; allergy to drugs; cardiovascular disease; renal disease and previous abdominal surgeries with adhesion band and fibrosis. 5) Intervention: prophylactic bolus dose administration or infusion of phenylephrine 6) Main outcome measures variables:spinal anesthesia induced blood pressure change

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601238768N4**
Registration date: **2016-10-09, 1395/07/18**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-10-09, 1395/07/18

Registrant information

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Mahshid Nikooseresht
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research and Technology, Hamadan University Of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-08-20, 1396/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between different prophylactic & therapeutic phenylephrine regimenes in reducing maternal hypotention after induction of spinal anesthesia in caesarean section

Public title

Evaluation of the effect of phenylephrine on spinal anesthesia induced hypotension in cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All of the ASA 1 healthy term parturients referring to Fatemieh hospital candidate for Cesarean section were included in the study. Exclusion criteria: chronic hypertension; pre eclampsia; twin pregnancy;, preterm labor; allergy to drugs; cardiovascular disease; renal disease and previous abdominal surgeries with adhesion band and fibrosis.

Age

From **16 years** old to **50 years** old

Gender

Female

Phase

2-3

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

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee of Ethics in Research, Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Street, Hamadan

City

Hamedan

Postal code

65178

Approval date

2016-01-23, 1394/11/03

Ethics committee reference number

IR.UMSHA.REC.1394.449

Health conditions studied

1

Description of health condition studied

spinal anesthesia induced hypotension

ICD-10 code

O74.6

ICD-10 code description

Other complications of spinal and epidural anaesthesia during labour and delivery

Primary outcomes

1

Description

spinal anesthesia induced blood pressure change

Timepoint

before performing spinal anesthesia, every 2 minutes until delivery and then every 5 minutes until the end of surgery

Method of measurement

blood pressure was measured with automatic blood pressure device and hypotension was defined as more than 20% decrease of BP compared to baseline

Secondary outcomes

1

Description

Heart rate

Timepoint

before performing spinal anesthesia and then every 5 minutes until the end of surgery

Method of measurement

Electrocardiogram monitoring

2

Description

nausea

Timepoint

every 5 minutes until the end of surgery

Method of measurement

observation

3

Description

vomiting

Timepoint

every 5 minutes until the end of surgery

Method of measurement

observation

4

Description
rescue vasopressor dose
Timepoint
at the end of surgery
Method of measurement
measurement

5

Description
Neonatal condition
Timepoint
at min 1 and 5
Method of measurement
Apgar score mesurements by observation and physical examination

Intervention groups

1

Description
Intervention1: after performing spinal anesthesia (with 10 milligram bupivacaine plus 25 micro-gram fentanyl) 100 microgram phenylephrin in 1 cc volume will be injected and then infusion of normal saline will be started and continued until delivery. In the case of hypotension 50 microgram phenylephrine will be injected.
Category
Treatment - Drugs

2

Description
Intervention 2: after performing spinal anesthesia (with 10 milligram bupivacaine plus 25 micro-gram fentanyl) normal saline in 1 cc volume will be injected and then infusion of phenylephrine 50 microgram per minute will be started and continued until delivery. In the case of hypotension 50 microgram phenylephrine will be injected.
Category
Treatment - Drugs

3

Description
Control group: after performing spinal anesthesia (with 10 milligram bupivacaine plus 25 micro-gram fentanyl) normal saline in 1 cc volume will be injected and then infusion of normal saline will be started and continued until delivery. In the case of hypotension 50 microgram phenylephrine will be injected.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh hospital
Full name of responsible person
Mahshid Nikooseresht
Street address
Pasdaran Street, Shariati square, Hamadan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research and Technology, Hamadan University Of Medical Sciences
Full name of responsible person
Saiid Bashirian
Street address
Hamadan University of Medical Science, Shahid Fahmideh street, Hamadan
City
Hamadan
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 and Technology, Hamadan 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
Hamadan University of Medical Sciences
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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