

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison between different prophylactic & therapeutic phenylephrine regimens in reducing maternal hypotension 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 Fatemeh 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

Name

Mahshid Nikooseresht

Name of organization / entity

Hamadan university of Medical Sciences, Faculty of Medicine

Country

Iran (Islamic Republic of)

Phone

+98 81 3823 5383

Email address

nikooseresht@umsha.ac.ir

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 regimens in reducing maternal hypotension 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 Fatemeh 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 measurements 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

City

Hamadan

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

Full name of responsible person

Mahshid Nikooseresht M.D

Position

Assistant Professor of Anesthesiology, Fellowship of Pain management

Other areas of specialty/work

Street address

Anesthesiology Department, Besat hospital, Shahid Motahari Blvd, Resalat Square, Hamadan

City

Hamadan

Postal code

6514845471

Phone

+98 81 3264 0049

Fax

Email

nikooseresht@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Mahshid Nikooseresht M.D

Position

Assistant Professor of Anesthesiology, Fellowship of Pain management

Other areas of specialty/work

Street address

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City

Hamadan

Postal code

6514845471

Phone

+98 81 3264 0050

Fax

Email

nikooseresht@umsha.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

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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