Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison between the effect of Phenylephrine versus Ephedrine on treatment of maternal hypotension & neonatal cord Venus blood analysis during caesarean section under spinal anesthesia with Bupivacaine

Protocol summary

Summary

The purpose of this study is comparison of Phenylephrine and Ephedrine on treatment of maternal hypotension and neonatal cord blood Gases analysis during caesarean section under spinal anesthesia with Bupivacaine.This study undergoing on 100 singleton pregnant women with gestational age of 37 weeks that are undergoing to spinal anesthesia with Bupivacaine for cesarean section. Patients are randomly divided into two groups P and E. Before spinal anesthesia both groups receive 500 ml Ringer. The arterial blood pressure, heart rate and blood oxygen saturation be measure and use as a basis. Three mL of 0.5% Hyperbaric Bupivacaine is injected in vertebral space L4-L5 in both groups. Immediately after spinal anesthesia, then every 5 minutes until 30 minutes and every 10 minutes until reduced sensation below the level of T10, arterial blood pressure, heart rate and blood oxygen saturation will be measured and recorded. If hypotension is more than 20% from baseline or a systolic blood pressure less than 100, 100 micro gram bolus Phenylephrine or 10 mg ephedrine inject. Bolus doses repeat if necessary. After the neonates delivery, the"1st and 5th minutes' Apgar scores" is recorded and umbilical venous blood samples are taken to evaluate acid-base status.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412046280N5**
Registration date: **2014-12-17, 1393/09/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-12-17, 1393/09/26

Registrant information

Name

Mohammad Haghighi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 13 3211 1319

Email address

mohaghighi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan university of medical sciences

Expected recruitment start date

2015-01-20, 1393/10/30

Expected recruitment end date

2015-04-30, 1394/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the effect of Phenylephrine versus Ephedrine on treatment of maternal hypotension & neonatal cord Venus blood analysis during caesarean section under spinal anesthesia with Bupivacaine

Public title

Effect of phenylephrine and ephedrine for treatment of hypotension during Caesarean

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age 18-40 years; MOM height 150-170 cm; Weight 60-90 kg; Gestational age 37-42 weeks; Singleton; ASA class 1, 2; Systolic blood pressure under 100 mmHg after spinal anesthesia Exclusion criteria: Severe respiratory distress; Cord prolapse; Decollement; Placenta prevail

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Ethics committee of Guilan university of Medical Science

Street address

Namjoo Street

City

Rasht

Postal code

4193893345

Approval date

2014-09-30, 1393/07/08

Ethics committee reference number

1930330303

Health conditions studied

1

Description of health condition studied

Maternal hypotension

ICD-10 code

O26.5

ICD-10 code description

Maternal hypotension

Primary outcomes

1

Description

Blood pressure

Timepoint

After spinal anesthesia, then every 5 minutes until 30 minutes and every 10 minutes until reduced sensation below the level of T10

Method of measurement

mmHg by Saadat monitoring system

2

Description

Oxygen saturation

Timepoint

Upon arrival to operating room , 3, 5, 10, 15 minutes after endotracheal intubatioin and 10 minutes after extubation

Method of measurement

Percent by pulse oximeter

3

Description

PH umblical vein

Timepoint

After birth

Method of measurement

by AVL

4

Description

Neonate APgar

Timepoint

First and five minutes after birth

Method of measurement

Apgar score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention1: Injection 100 micro ggram phenylephrine if hypotension is more than 20% from baseline or a systolic blood pressure less than 100

Category

Treatment - Drugs

2

Description

Intervention 2: Injection 10 mg ephedrine if hypotension is more than 20% from baseline or a systolic blood pressure less than 100

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Mohammad Haghighi

Street address

Namjoo Street

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Guilan University of Medical Sciences

Full name of responsible person

Abtin Heidarzadeh

Street address

Shahid beheshti Highway

City

Rasht

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 of Guilan University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Full name of responsible person

Street address

City

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Proportion provided by this source

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

Guilan University of Medical Sciences

Full name of responsible person

Mohammad Haghighi

Position

Anesthesiologist/ Associated Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Anesthesiologist/Assosiated proffessor

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Medical laboratory Sciences Technician/ Bachelor's Degree

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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