Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of norepinephrine, ephedrine and phenylephrine on prophylaxis and treatment of hemodynamic changes of spinal anesthesia in elective Caesarean section surgeries

Protocol summary

Study aim

Comparing the effect of norepinephrine ephedrine and phenylephrine on prophylaxis and treatment of hemodynamic changes of spinal anesthesia such as systolic blood pressure, diastolic blood pressure , pulse rate , nausea and vomiting in elective Caesarean section surgeries

Design

A concealed, randomized, blinded controlled clinical trial with 3 groups design of 45 patients enrolled between March 2021 and August 2021

Settings and conduct

Patients get divided into 3 groups of N, P and E respectively. The patients will be monitored and an iv line for serum therapy will be administered. After receiving 5cc per kilograms of ringer lactate serum spinal anesthesia with proper positioning and sterile preparation with 25 gauge needle with midline approach through L3 - L4 space will be done . According to patients height 0.5 % bupivacaine will be administered. 5 micrograms of norepinephrine in group N , 40 micrograms of phenylephrine in group P and 5 milligrams of ephedrine in group E will be administered the vital signs will be charted every one minute till birth then every 5 minutes till the end of surgery.This sampling is done randomly for the patients who are referred to Rasoul Akram and Firouzgar hospital in Tehran .

Participants/Inclusion and exclusion criteria

Patient consent , age 18 - 40 , height >150 centimeters, gestational age > 36 weeks , weight 60 kilograms - 80 kilograms , no known medical conditions such as hypertension

Intervention groups

The patients will be divided randomly into 3 groups after reviewing the consent papers , basic monitoring and spinal block will be done for each respectively. One of the 3 mentioned drugs will be administered in each group then the vital signs will be charted every 5 minutes.

Main outcome variables

Blood pressure Heart rate Nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210204050243N1**
Registration date: **2021-05-07, 1400/02/17**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-07, 1400/02/17**
Update count: **0**

Registration date

2021-05-07, 1400/02/17

Registrant information

Name

Rima Al Ghozat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2214 7094

Email address

rimaghozat1989@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of norepinephrine, ephedrine and phenylephrine on prophylaxis and treatment of hemodynamic changes of spinal anesthesia in elective Caesarean section surgeries

Public title

Evaluation of the effect of norepinephrine, ephedrine and phenylephrine in treatment of hemodynamic changes in spinal anesthesia in Caesarean section surgeries

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patient consent Gestational age >36 wks Height>150 cm Age 18 -40 years Weight 60 kg - 80 kg

Exclusion criteria:

Spinal block failure Preeclampsia History of hypertension Gestational age of < 36 wks Multiple gestation Height < 150 cm Opium addiction Contraindication of spinal anesthesia History of heart disease Patient discontent

Age

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

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

In this current study a permuted block randomization technique will be used in which the randomization will be conducted right before the patients admission. Taking in consideration that 45 patients will be participated in this study which will be divided in 15 blocks each with three sections. First of all 15 blocks each with three sections , in each different methods of treatment included, will be conducted. After forming 15 blocks , all of them will be put in a non transparent envelope and then in a specific vase. Then in each stage an envelope will be selected randomly and will be registered in a predetermined table. For instance, the combination of the first block will be N,P,E in which the first patient will receive the treatment in group N and the second will receive the treatment in group P and the third will receive the treatment in group E, and this will continue until all 15 blocks will be selected. All of these steps will be done before sampling . For allocation concealment, the blocks will be put in a non transparent envelope with no names of the drugs that will be used in this study mention on the envelope. The intervention of the first patient will be unknown until the sampling is completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double blinded study in which both the participants and the investigators will not be informed on grouping the patients and the related outcomes

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Rasoul Akram hospital, Maziyar Mansouri street , Sattar Khan

City

Tehran

Province

Tehran

Postal code

1998733191

Approval date

2020-11-01, 1399/08/11

Ethics committee reference number

IR.IUMS.FMD.REC.1399.475

Health conditions studied

1

Description of health condition studied

Hemodynamic changes of spinal anesthesia

ICD-10 code

O74.5

ICD-10 code description

Spinal and epidural anesthesia-induced headache during labor and delivery

Primary outcomes

1

Description

The percentage of women with low blood pressure and heart rate

Timepoint

Right after basic monitoring then every one minute right after the spinal anesthesia is done till the birth and then

every five minutes till the end of the surgery

Method of measurement

Blood pressure monitor and pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 : Right after spinal anesthesia is done 5 micrograms of norepinephrine will be administered then the patient's vital signs will be documented every one minute till birth then every 5 minutes till end of surgery.

Category

Prevention

2

Description

Intervention group2: Right after spinal anesthesia is done 40 micrograms of phenylephrine will be administered then the patient's vital signs will be documented every one minute till birth then every 5 minutes till end of surgery.

Category

Prevention

3

Description

Intervention group3: Right after spinal anesthesia is done 5 milligrams of ephedrine will be administered then the patient's vital signs will be documented every one minute till birth then every 5 minutes till end of surgery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Dr Rima Al Ghozat

Street address

Maziyar Mansouri st, Sattar Khan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Abbas Motevalian

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Iran medical university, Hemmat highway

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1449614536

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Rima Alghozat

Position

Anesthesiology resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable