

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of the treatment of spinal anesthesia induced hypotension by Ephedrine or Phenylephrine on the Neonatal Arterial Blood Gas and Apgar score in Cesarean Delivery of Obese Parturient

Protocol summary

Summary

In current double-blinded randomized clinical trial, we aim to compare effect of ephedrine and phenylephrine on arterial blood gas status and fetal APGAR (appearance, pulse, grimace, activity, respiration) in treatment of the epidural anesthesia induced hypotension in obese mothers undergo cesarean section. In current interventional study, among 120 patients candidate for elective cesarean section that will be divided two groups consisting 60 patients, frequency of hypotension incidence, duration of hypotension, number of vasopressor drugs injection and overall doses of administrated vasopressor drugs will be compared. In case of patients' consent, obese women with single term pregnancy and candidate for cesarean section and epidural anesthesia enrolled study diabetic women and women suffering gestational hypertension or contraindications for epidural anesthesia excluded. Patients randomly assigned to two groups of the study designed for epidural anesthesia induced hypotension treatment by ephedrine or phenylephrine, using a software which provided sealed envelope method. In case of systolic blood pressure decrease to less than 90 mmHg or diminish to more than 30 percent of its baseline, subsequent to increase the intravenous fluid infusion speed, in phenylephrine group, 50 micrograms intravenous phenylephrine will be administrated up to 200 micrograms and in ephedrine group, 5-10 milligram intravenous ephedrine will be administrated up to 20 milligrams. Afterward, results of the umbilical artery blood gas analysis and neonates first and fifth minutes APGAR scores gathered and all data will be recorded in a questionnaire in order to compare values between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062028545N1**
Registration date: **2016-09-10, 1395/06/20**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-09-10, 1395/06/20

Registrant information

Name

Solmaz Fakhari

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3332 1454

Email address

fakhariso@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and development of Tabriz University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the treatment of spinal anesthesia induced hypotension by Ephedrine or Phenylephrine on the Neonatal Arterial Blood Gas and Apgar score in Cesarean Delivery of Obese Parturient

Public title

Comparing effect of the spinal anesthesia induced hypotension treatments on neonatal factors

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: interest to participate in study; obesity (BMI30 kg/m²); no underlying diseases except obesity; Class II category in ASA grading system; age between 18-40; term pregnancy; singleton pregnancy; candidate for elective cesarean section; candidate for epidural anesthesia. Exclusion criteria: emergency cesarean section; diabetic mother; no consent to participate in study; gestational hypertension; epidural anesthesia contraindications; twin pregnancy; need to change epidural anesthesia to general anesthesia; intraoperative bleeding more than 1000 milliliter; neonate birth body weight less than 2500 grams.

Age

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

Gender

Female

Phase

N/A

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**

Not used

Assignment

Parallel

Other design features

Software used to randomize samples using sealed envelope method

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of the research and technology

department, Tabriz University of Medical sciences

Street address

Research department- Daneshgah street- Tabriz

City

Tabriz

Postal code**Approval date**

2016-02-08, 1394/11/19

Ethics committee reference number

IR.TBZMED.REC.1394.1039

Health conditions studied**1****Description of health condition studied**

Other complications of spinal and epidural anaesthesia during labour and delivery

ICD-10 code

O74.6

ICD-10 code description

Other complications of spinal and epidural anaesthesia during labour and delivery

Primary outcomes**1****Description**

Umbilical artery blood pH

Timepoint

Right after neonate birth

Method of measurement

Arterial blood gas test

2**Description**

Umbilical artery blood pO₂

Timepoint

Right after neonate birth

Method of measurement

Arterial blood gas test

3**Description**

Umbilical artery blood pCO₂

Timepoint

Right after neonate birth

Method of measurement

Arterial blood gas test

Secondary outcomes**1****Description**

APGAR

Timepoint

APGAR in the first minute after delivery

Method of measurement

APGAR scoring system

2

Description

APGAR

Timepoint

APGAR in the fifth minute after delivery

Method of measurement

APGAR scoring system

Intervention groups

1

Description

Ephedrine administration: injection of 5-10 milligram intravenous ephedrine up to 20 milligram, as vasopressor in case of hypotension.

Category

Treatment - Drugs

2

Description

Phenylephrine: injection of 50 micrograms intravenous ephedrine up to 200 microgram, as vasopressor in case of hypotension.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Taleghani hospital

Full name of responsible person

Dr. Solmaz Fakhari

Street address

Taleghani hospital, Rah ahan square, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Tabriz University of Medical Sciences, Daneshgah Street, Tabriz

City

Tabriz

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 Tabriz 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

Medicine faculty

Full name of responsible person

Hassan Soleiman Pour

Position

Vice Chancellor for research of Medicine faculty

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Name of organization / entity

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Position

Assistant Professor in Anesthesiology

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Fax**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