Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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- Daneshghah 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
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Person responsible for updating data

Contact

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Position
Assistant Professor in Anesthesiology

Other areas of specialty/work

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City
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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