Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

A study of effect of prophylactic intravenous ephedrine on fetal and neonatal heart rate in emergency cesarean delivery due to fetal bradycardia

Protocol summary

Study aim

Determination of the effect of prophylactic intravenous ephedrine injection to mother on fetal and neonatal heart rate in emergency cesarean delivery due to fetal bradycardia

Design

A prospective randomized controlled trial (RCT) with two parallel groups, double-blind

Settings and conduct

In Tabriz Alzahra hospital in 1398, the effect of prophylactic ephedrine injection to mother on the fetal and neonatal heart rate in 96 cases of cesarean section due to fetal bradycardia, will be evaluated in randomly assigned to ephedrine and placebo groups. Patients and data recorders will be blinded to the study.

Participants/Inclusion and exclusion criteria

96 term parturient aged 18 to 45 years with the physical status of the American Society of Anesthesiologists (ASA) I, II candidates for emergency cesarean with spinal anesthesia due to fetal bradycardia with informed consent. Any contraindication of regional anesthesia and maternal coexisting disease will be excluded.

Intervention groups

The effect of prophylactic ephedrine on fetal and neonatal heart rate in the intervention group (ephedrine) (n = 48) and the control group (placebo) (n = 48) would be compared.

Main outcome variables

The fetal heart rate before and after the intervention, and the neonatal heart rate in the 1, 5, 10th minutes of birth; neonatal arterial blood gases; APGAR score in the 1, 5, 10th minutes of birth; admission rate of the neonate in NICU; maternal blood pressure and the need for additional ephedrine will be recorded.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180411039267N3**
Registration date: **2019-07-13, 1398/04/22**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-13, 1398/04/22**
Update count: **0**

Registration date

2019-07-13, 1398/04/22

Registrant information

Name

Reyhaneh Abri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3476 7121

Email address

re.abri@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-01, 1398/03/11

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A study of effect of prophylactic intravenous ephedrine on fetal and neonatal heart rate in emergency cesarean delivery due to fetal bradycardia

Public title
Effect of ephedrine on fetal and neonatal heart rate in emergency cesarean delivery due to fetal bradycardia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Term pregnancy Physical status of American society of Anesthesiology (ASA) class I or II fetal bradycardia candidate for emergency cesarean with spinal anesthesia Informed consent 18 to 45 years old

Exclusion criteria:
Contraindication of regional anesthesia Gestational hypertension, preeclampsia, eclampsia HELLP syndrome (Hemolysis, increased liver enzyms, low platelet) Maternal co-existing disease such as heart disease which ephedrine administration is contraindicated Emergency Cesarean section due to peripartum hemorrhage, umbilical cord prolapse

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
The cases will be randomly divided into two groups of 48 people in the study group and 48 people in the control group using random numbers table. In the event of odd, they would be placed in the ephedrine group and in the event of even, they would be placed in the placebo group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The administration of anesthesia and serum before and during anesthesia is performed by an anesthesiologist and anesthesia technician. So that one ml of bolus intravenous ephedrine (equivalent to 10 mg) is injected into the study group and one ml of sodium chloride 0.9% as a placebo is injected into the placebo group. Then, all data will be collected and recorded in the checklist by an other anesthesiologist who is unaware of the injected drug type and the division of the groups and is not in charge of anesthesia management. Pregnant women undergoing cesarean section are also unaware of the division of the groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Department of Anesthesiology, Alzahra hospital, South artesh street

City
Tabriz

Province
East Azarbaijan

Postal code
5174815811

Approval date
2018-10-08, 1397/07/16

Ethics committee reference number
IR.TBZMED.REC.1397.574

Health conditions studied

1

Description of health condition studied
fetal bradycardia, prophylactic intravenous ephedrine, emergency cesarean delivery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
fetal and neonatal heart rate

Timepoint
Measuring fetal heart rate at the entrance to the operating room, one minute after ephedrine or placebo injection, immediately after the spinal anesthesia, measuring the neonatal heart rate immediately, 5 and 10 minutes after birth

Method of measurement
The fetal heart rate is measured by sonochade and neonatal heart rate by pulse oximeter and will be recorded in the checklist prepared for this purpose.

Secondary outcomes

1

Description
APGAR score in the 1, 5, 10th minutes of birth
Timepoint
in the 1, 5, 10th minutes after birth
Method of measurement
Observe and examination of the baby in minutes 1, 5 and 10

2

Description
admission rate of the neonate in NICU
Timepoint
While baby's transfer to the neonatal ward or NICU
Method of measurement
Record from the patient file

3

Description
neonatal arterial blood gases
Timepoint
Immediately after clamp of umbilical cord
Method of measurement
neonatal arterial blood gases analysis

4

Description
maternal blood pressure and the need for additional ephedrine
Timepoint
Every 2 minutes up to 10 minutes, then every 5 minutes up to 30 minutes, and then every 10 minutes until the end of operation
Method of measurement
Measurement by non-invasive barometer cuff of vital signs monitoring device

Intervention groups

1

Description
Intervention group: In 48 pregnant women with fetal bradycardia, as soon as mother's arrival into the operating room and after initial monitoring, one ml of intravenous ephedrine equivalent to 10 mg will be injected to the mother and its effect on the fetal and neonatal heart rate will be examined.
Category
Treatment - Drugs

2

Description
Control group: In 48 pregnant women with fetal bradycardia, as soon as mother's arrival into the operating room and after initial monitoring, one ml of intravenous sodium chloride 0.9% as a placebo will be injected to the mother and its effect on the fetal and neonatal heart rate will be examined.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Reyhaneh Abri
Street address
Alzahra hospital, South artesh street
City
Tabriz
Province
East Azarbaijan
Postal code
5138663134
Phone
+98 41 3553 9163
Email
alzahrahosp@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Abolghasem Jouyban
Street address
International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Phone
+98 41 3335 7310
Email
research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Reyhaneh Abri
Position
Assisstant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Department of Anesthesiology, Alzahra Hospital, South Artesh Street
City
Tabriz
Province
East Azarbaijan
Postal code
5174815811
Phone
+98 41 3553 9163
Email
reyhane.abri@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Reyhaneh Abri
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Department of Anesthesiology, Alzahra Hospital, South Artesh Street
City
Tabriz
Province
East Azarbaijan
Postal code
5174815811
Phone
+98 41 3553 9163
Fax
Email
reyhane.abri@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Reyhaneh Abri
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Operating room-alzahra hospital- south artesh st
City
Tabriz
Province
East Azarbaijan
Postal code
5138663134
Phone
+98 41 3476 7121
Fax
Email
reyhane.abri@gmail.com

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
Undecided - It is not yet known if there will be a plan to make this available
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available