Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of glucose containing crystalloid infusion on maternal hemodynamic status during spinal anesthesia for cesarean section

Protocol summary

Summary

Considering glucose infusion effects during surgery, in current double-blinded randomized clinical trial, we aimed to evaluate effect of glucose addition to ringer solution on maternal hemodynamic status subsequent to epidural analgesia cesarean section. Ninety women aged between 18 to 40 years old with term singleton pregnancy candidate for elective cesarean section with epidural analgesia will be enrolled and women suffering systemic diseases, mental disorders and body mass index more than 30 kilograms per meter square will be excluded. Prior to surgery, equally, patients will be divided to control and study groups, by randomization. Study group (45 cases) will receive 1% glucose solution in ringer serum, and control group (45 cases) will receive distilled water added to ringer serum. During administration of epidural analgesia, 8 ml/kg body weight bullous intravenous fluid will be infused during 15 minutes and subsequently, infusion will be continued till end of the operation in dose of 15-20 ml/kg/ min. Study group solution (1% glucose) will be prepared by adding 10 gram of glucose (20 ml) to 1-liter ringer serum and control group solution will be prepared by adding same amount of distilled water to ringer serum, as well. Study parameters including basal hemodynamic variables (blood pressure, heart rate) and prevalence of hypotension side effects including nausea, vomiting and respiratory suppression will be recorded. Overall vasopressors dosage and preoperative and postoperative maternal blood glucose level will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702077013N17**
Registration date: **2017-02-18, 1395/11/30**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-02-18, 1395/11/30

Registrant information

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Simin Atashkhoei
Name of organization / entity
Tabriz University of Medical Siences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of research, Tabriz University of Medical Sciences

Expected recruitment start date

2017-02-11, 1395/11/23

Expected recruitment end date

2017-08-14, 1396/05/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of glucose containing crystalloid infusion on maternal hemodynamic status during spinal anesthesia for cesarean section

Public title

Glucose containing crystalloid effect on hemodynamic status during cesarean section

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: class I in American society of anesthesiology; aged between 18-40 years old; term pregnancy; singleton pregnancy; candidate for elective cesarean section; candidate for epidural analgesia.
Exclusion criteria: emergent cesarean section; systemic diseases (renal, cardiac, pulmonary, hepatic, neuromuscular and etc.); mental disorders; body mass index more than 30 kilograms per meter square; history of glucose intolerance; consumption of drugs effecting glucose metabolism; allergy to bupivacaine; contraindications for epidural analgesia; fetal complication (asphyxia, meconium stained amniotic fluid).
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Single
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
Vice chancellor for research, Tabriz university of medical sceinces, Daneshgah square
City
Tabriz
Postal code
Approval date
2017-01-15, 1395/10/26
Ethics committee reference number
IR.TBZMED.REC.1395.1110

Health conditions studied

1

Description of health condition studied
Hemodynamic changes during cesarean section by epidural analgesia
ICD-10 code
O74.9
ICD-10 code description
Complication of anaesthesia during labour and delivery, unspecified

Primary outcomes

1

Description
Systolic blood pressure
Timepoint
each 2 minutes till fetal birth, then each 5 minutes till end of the operation
Method of measurement
measuring patients blood pressure

2

Description
Dyastolic blood pressure
Timepoint
each 2 minutes till fetal birth, then each 5 minutes till end of the operation
Method of measurement
measuring patients blood pressure

3

Description
Mean arterial pressure
Timepoint
each 2 minutes till fetal birth, then each 5 minutes till end of the operation
Method of measurement
calculating using mean arterial pressure formula

4

Description
Heart rate
Timepoint
each 2 minutes till fetal birth, then each 5 minutes till end of the operation
Method of measurement
Using pulseoxymetery

Secondary outcomes

1

Description
maternal blood glucose
Timepoint

before operation, after operation

Method of measurement

using blood sugar glucometer

2

Description

measurement the dosage of vasopressor agents used

Timepoint

after operation

Method of measurement

measuring dosage of vasopressor agents used

Intervention groups

1

Description

Control group: Placebo group solution will be prepared by adding 20 ml distilled water to 1-liter ringer serum. During administration of epidural analgesia, 8 ml/kg body weight bullous intravenous fluid will be infused during 15 minutes and subsequently, infusion will be continued till end of the operation in dose of 15-20 ml/kg/ min

Category

Treatment - Other

2

Description

Study group: Study group solution will be prepared by adding 20 ml glucose (10 gram) glucose to 1-liter ringer serum. During administration of epidural analgesia, 8 ml/kg body weight bullous intravenous fluid will be infused during 15 minutes and subsequently, infusion will be continued till end of the operation in dose of 15-20 ml/kg/ min

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al Zahra Women's Hospital

Full name of responsible person

Dr. Simin Atashkhoyi

Street address

Baghshomal crossroad, North artesh street, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Ostadrahimi

Street address

Vice chancellor for research, Tabriz University of medical sceinces, Daneshgah square

City

Tabriz

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

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Simin Atashkhoyi

Position

Professor, Specialist in Anesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

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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