

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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

Name

Simin Atashkhoei

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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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 sciences, 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 pulseoxymetry

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 sciences, 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

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Position

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Other areas of specialty/work

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Postal code

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