Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

The effect of crystalloid infusion containing 2% glucose on hemodynamic status in cesarean section with spinal anesthesia

Protocol summary

Study aim
Determination of the effect of infusion of crystalloid containing 2% glucose on hemodynamic status in cesarean section with spinal anesthesia

Design
This is a parallel double-blind randomized clinical trial study in which 40 eligible patients will be randomly assigned to two intervention and control groups

Settings and conduct
This study is conducted in Fatemieh Teaching, Research and Treatment Hospital in Hamadan city on 40 pregnant women candidates for elective cesarean section. The intervention group received 2% glucose solution in Ringer's serum and the control group received only Ringer's solution. Basic hemodynamic values are recorded before and immediately after the spinal and every 2 minutes to the first ten minutes and then every 10 minutes until the end of the procedure. Glucose level is measured through capillary blood sample before intravenous infusion and at the end of surgery. The capillary blood sample of the baby is measured through the heel immediately after birth and one hour later

Participants/Inclusion and exclusion criteria
Pregnant women between the ages of 18 and 45 who have a singleton pregnancy with a gestational age of 37 to 42 weeks and are candidates for elective cesarean section Failure to enter: Any underlying disease or history of diabetes, Obesity and allergy to marcaine and twin pregnancy or emergency cesarean section

Intervention groups
Intervention group: receive Ringer's solution containing glucose control group: receive Ringer's solution containing placebo (normal saline).

Main outcome variables
Comparison of hemodynamic changes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160523028010N2**
Registration date: **2022-09-04, 1401/06/13**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-04, 1401/06/13**
Update count: **0**

Registration date
2022-09-04, 1401/06/13

Registrant information

Name
Pouran Hajian

Name of organization / entity
Hamedan University of Medical Sciences

Country
Iran (Islamic Republic of)

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hajian@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-06, 1401/05/15

Expected recruitment end date
2023-03-06, 1401/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of crystalloid infusion containing 2% glucose on hemodynamic status in cesarean section with spinal

anesthesia

Public title
The effect of crystalloid infusion containing 2% glucose on blood pressure and heart rate in cesarean section with spinal anesthesia
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 -45 year Gestational age (38-42 week) Single tone pregnancy Elective cesarean under spinal anesthesia ASA I Consent to participate in the study
Exclusion criteria:
psychotic disorders BMI>35kg/m2 Emergency cesarean Systemic diseses(renal,cardiac,pulmonary,hepatic, musculoskeletal ,... disorders) Intolerance to glucose Taking drugs that affect glucose metabolism Contraindications to spinal anesthesia Allergy to bupivacaine
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
For this purpose, the envelope method will be used. For this purpose, four sheets of paper were prepared. The letter I will be written on two sheets and the letter C will be written on the other two sheets. The leaves are placed in the envelope and after mixing, we will put them in the table drawer. Upon referral to any of the eligible patients, one of the sheets will be randomly pulled out and based on this sheet, I or C will be assigned to one of the two intervention groups (I and control (C)). When all four sheets are accidentally pulled out, all the sheets will be returned to the drawer and the above operation will be continued for the next four patients until the desired sample size is reached.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In both groups I and C, serums containing glucose and distilled water are prepared and injected by the nurse, so the anesthesiologist who will measure and record the study outcome, also the person undergoing cesarean section will not know the type of drug prescribed did not have.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences
Street address
Hamadan University of Medical Science, Shahid Fahmideh Blvd
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2022-05-08, 1401/02/18
Ethics committee reference number
IR.UMSHA.REC.1401.137

Health conditions studied

1

Description of health condition studied
Hemodynamic change during cesarean
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Changes in blood pressure
Timepoint
Upon arrival, before and immediately after the spinal and every 2 minutes to the first ten minutes and then every 10 minutes until the end of the operation was recorded.
Method of measurement
Standard monitoring device

2

Description
changes of Heart rate
Timepoint
Upon arrival, before and immediately after the spinal and every 2 minutes to the first ten minutes and then every 10 minutes until the end of the operation was recorded.
Method of measurement
Standard monitoring device

3

Description
percent of patient with blood pressure less than 90 mmHg
Timepoint
none
Method of measurement
Standard monitoring device

4

Description
percent of patient with heart rate less than 50 per minute
Timepoint
none
Method of measurement
Standard monitoring device

Secondary outcomes

1

Description
Nausea and vomiting
Timepoint
Every two minutes for ten minute and then every ten minute until end of surgery
Method of measurement
through observation

2

Description
chills through observation
Timepoint
Every two minutes for ten minute and then every ten minute until end of surgery
Method of measurement
through observation

3

Description
Hypoglycemia or hyperglycemia in mother
Timepoint
before surgery and at the end of surgery,
Method of measurement
based on Glucometery measurements

4

Description
Hypoglycemia or hyperglycemia in infant
Timepoint
immediately after birth and one hour after birth.
Method of measurement
based on Glucometery measurements

Intervention groups

1

Description
Intervention group: pregnant women receiving Ringer's serum containing 2% glucose20 grams of glucose are added per liter of Ringer's serum, after the pregnant woman is placed on the surgical bed, the infusion of Ringer's serum containing glucose starts and continues until the end of the surgery. The mother's blood sugar is measured before and after the surgery.The baby's blood sugar is checked immediately after birth and one hour after that.Systolic blood pressure, diastolic blood pressure, mean arterial pressure and heart rate are measured before the start of spinal anesthesia, immediately after spinal anesthesia, every two minutes to ten minutes, and then every ten minutes until the end of the surgery. Shivering, nausea and vomiting, if any, are recorded until the end of the operation. If the systolic pressure is less than 90 mmHg, 20-5 mg of ephedrine and the heart rate is less than 50 per minute, 0.5 mg of atropine is injected.
Category
Prevention

2

Description
Control group: pregnant women receiving Ringer's serum Normal saline is added per liter of Ringer's serum, equivalent to the volume of glucose added in the intervention group. After the pregnant woman is placed on the surgical bed, Ringer's serum infusion starts and continues until the end of the surgery. The mother's blood sugar is measured before and after the surgery. The baby's blood sugar is checked immediately after birth and one hour after that, systolic, diastolic and average blood pressure and heart rate are measured before starting spinal anesthesia, immediately after spinal anesthesia, every two minutes to ten minutes, and then every ten minutes until the end of surgery. Shivering, nausea, and vomiting, if any, are recorded until the end of the procedure. If the systolic pressure is less than 90 mmHg, 20-5 mg of ephedrine and the heart rate is less than 50 per minute, 0.5 mg of atropine is injected.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Anesthesiolgy Department, Fatemieh hospital, ,Pasdaran street , Shariati Square
Full name of responsible person
Pouran Hajian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Pouran Hajian
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
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Other areas of specialty/work
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Person responsible for updating data

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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