

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 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 Fatemeh 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)

Phone

+98 81 3838 0312

Email address

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 diseases(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 Glucometry measurements

4

Description

Hypoglycemia or hyperglycemia in infant

Timepoint

immediately after birth and one hour after birth.

Method of measurement

based on Glucometry measurements

Intervention groups

1

Description

Intervention group: pregnant women receiving Ringer's serum containing 2% glucose 20 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

Anesthesiology Department, Fatemeh hospital, Pasdaran street, Shariati Square

Full name of responsible person

Pouran Hajian

Street address

Fatemeh Hospital Pasdaran St. Shariati Sq.

City

Hamadan

Province

Hamadan
Postal code
6517838695
Phone
+98 81 3828 3905
Email
hajian@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Reza Shokoohi
Street address
Hamadan University of Medical Science, Shahid
Fahmideh Bolvardt,
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0717
Email
info.research@umsha.ac.ir

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
Pouan Hajian
Position
Associate Professor
Latest degree
Specialist

Other areas of specialty/work

Anesthesiology

Street address

Hamadan university of medical sciences Faculty of
medicine ,Shahid Fahmideh Blvd

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

hajian@umsha.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Pouan Hajian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Hamadan University of Medical Science, Faculty of
medicine; Shahid Fahmideh Blvd

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0572

Email

hajian@umsha.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Pouan Hajian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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medicine

City

Hamadan

Province

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Postal code

6517838695

Phone

+98 81 3838 0572

Email

hajian@umsha.ac.ir

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