Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Prophylactic administration of ephedrine and hydroxyethyl starch before spinal anesthesia to prevent hypotension in patients undergoing cesarean section

Protocol summary

Study aim

Determining and comparing the effectiveness of prophylactic administration of ephedrine and hydroxyethyl starch before spinal anesthesia in preventing hypotension in patients undergoing cesarean section

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 120 patients. A table of random numbers was used for randomization.

Settings and conduct

The study will be conducted in Hajar Hospital, the participants and the statistical consultant will not know which of the study groups the participants are in. All patients receive 500 ml of balanced saline solution in advance. After spinal anesthesia with 15 mg hyperbaric bupivacaine 0.5%, patients will be turned on their back to avoid aorta-vena cava compression syndrome. All patients will receive 4 L/min of oxygen by face mask. In case of hypotension, 10 mg of ephedrine and intravenous crystalloid liquid will be prescribed. Hemodynamic changes, incidence of hypotension, reactive blood pressure, nausea and vomiting, intraoperative bleeding and Apgar score will be recorded in 1 and 5 minutes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: participants with full-term pregnancies who are elective for cesarean section and do not have any underlying disease. Exclusion criteria: the presence of one of the diseases associated with pregnancy, sensitivity to ephedrine and hydroxyethyl starch or similar drugs, BMI higher than 30, and addiction to amphetamine, cocaine, and LSD compounds.

Intervention groups

1) Ephedrine group: receiving 10 mg intravenous bolus of ephedrine 2) Hydroxyethyl starch group: receiving 500 ml of hydroxyethyl starch 3) Ephedrine and hydroxyethyl starch group: receiving 500 ml of hydroxyethyl starch and after spinal anesthesia, 10 mg intravenous bolus of ephedrine 4) Control group: receiving 500 ml Ringer's lactate infusion

Main outcome variables

Blood pressure drop

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230516058204N1**
Registration date: **2023-08-05, 1402/05/14**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-05, 1402/05/14**
Update count: **0**

Registration date

2023-08-05, 1402/05/14

Registrant information

Name

zahra heidari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3339 8456

Email address

st-heidari@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-11, 1402/04/20

Expected recruitment end date

2024-03-10, 1402/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prophylactic administration of ephedrine and hydroxyethyl starch before spinal anesthesia to prevent hypotension in patients undergoing cesarean section

Public title

The effect of ephedrine and hydroxyethyl starch in the prevention of hypotension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having an ASA Class I, II term pregnancy (American Society of Anesthesiologists) Participants in the study should refer electively for caesarean section Consent to participate in the study Absence of any underlying disease Absence of contraindications for spinal anesthesia

Exclusion criteria:

Presence of one of the diseases associated with pregnancy, such as gestational hypertension, gestational diabetes, fetal problems, and bleeding in the third trimester of pregnancy. Allergy to ephedrine and hydroxyethyl starch or similar drugs BMI higher than 30 Gestational age less than 37 weeks Known hypertension Known heart or lung disease Known liver or kidney disease Addiction to amphetamine, cocaine and LSD

Age

From **15 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomly assign patients in the groups under investigation, the permutation block method will be used. The sample size in each block will be equal to 8, and the randomization list will be prepared by the Random Allocation software and will be given to a person who does not know the intervention content of the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Since the study is a double-blind study, the participants and the statistical consultant will not know which of the study groups the participants are in.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

No. 16, 1 alley, Kashani Blvd.

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713564

Approval date

2023-02-08, 1401/11/19

Ethics committee reference number

IR.SKUMS.MED.REC.1401.063

Health conditions studied

1

Description of health condition studied

Low blood pressure

ICD-10 code

O82.9

ICD-10 code description

Delivery by caesarean section, unspecified

Primary outcomes

1

Description

Blood pressure drop

Timepoint

During the operation

Method of measurement

By using the monitoring device

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: immediately after spinal anesthesia, they will receive 10 mg intravenous bolus of ephedrine.
Category
Treatment - Drugs

2

Description
The second intervention group: just before spinal anesthesia, they will receive 500 ml of hydroxyethyl starch.
Category
Treatment - Drugs

3

Description
The third intervention group: before spinal anesthesia, they will receive 500 ml of hydroxyethyl starch and immediately after spinal anesthesia, they will receive 10 mg of ephedrine intravenous bolus.
Category
Treatment - Drugs

4

Description
Control group: They will receive 500 ml of Ringer lactate infusion just before spinal anesthesia.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان هاجر
Full name of responsible person
آزاده بهادری
Street address
Hajar hospital, Parastar St.
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Postal code
8816854633
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+98 38 3222 5505
Email
Hajar-Hospital@SKUMS.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Elham Raeisi
Street address
Vice Chancellory for Research and Technology, Shahrekord University of Medical Sciences, Kashani Blvd., Shahrekord, Iran
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Province
Chahar-Mahal-va-Bakhtiari
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8815713471
Phone
+98 38 3334 9509
Email
elhamraeisi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Zahra Heidari
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Main outcome information

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Only for researchers working in academic and scientific institutes

Under which criteria data/document could be used
to be used in future studies

From where data/document is obtainable
Zahra Heidari dr_zahra_heidari@yahoo.com

What processes are involved for a request to access data/document
Presenting documents of working in academic and scientific institutions

Comments