

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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.

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816854633

Phone

+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

City

shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

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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No. 16, 1 alley, Kashani Blvd.

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dr_zahra_heidari@skums.ac.ir

Person responsible for scientific inquiries

Contact

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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