

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### A randomized study to compare the sensory levels of spinal anesthesia for elective cesarean section using crystalloid versus Voluven solution

#### Protocol summary

##### Study aim

Comparison of crystalloid with colloid in sensory level induced by spinal anesthesia in cesarean section

##### Design

Clinical trial without control group, with parallel groups, double-blind, randomized, phase 3 on 120 patients. G\*Power software and permutation blocks method are used for randomization. The random numbers obtained are written on the card and each card is placed inside an opaque envelope and sealed.

##### Settings and conduct

In the operating room of Imam Hossein (AS) hospital in Tehran, an anesthesia technician, without the knowledge of the anesthesiologist and the patient, determined the patient group by randomly selecting a card and giving one of the solutions of each group to the anesthesiologist and records this information. Another anesthesiologist administers spinal anesthesia to the patient inside the operating room. Finally, the questionnaire is delivered to the first technician.

##### Participants/Inclusion and exclusion criteria

All pregnant mothers who are candidates for elective caesarean section refer to the operating room of Imam Hossein (AS) hospital and have singleton pregnancy, gestational age more than 36 weeks, height more than 150 and less than 175 cm, body mass index less than 35 kg/m square and have given written consent to conduct the study.

##### Intervention groups

Patients will be divided into three groups. In the normal saline group, within thirty minutes before the spinal anesthesia, the anesthesiologist will inject 10 ml/kg of 0.9% sodium chloride solution into the patient intravenously. In Ringer's group, the anesthesiologist will inject 10 ml/kg of Ringer's solution intravenously within thirty minutes before spinal anesthesia. In the Voluven group, within thirty minutes before spinal anesthesia, the anesthesiologist will inject 5 ml/kg of Volvone solution to the patient intravenously.

#### Main outcome variables

Sensory level obtained after spinal anesthesia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120910010800N10**

Registration date: **2023-01-15, 1401/10/25**

Registration timing: **prospective**

Last update: **2023-01-15, 1401/10/25**

Update count: **0**

##### Registration date

2023-01-15, 1401/10/25

##### Registrant information

##### Name

Dariush Abtahi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2263 2611

##### Email address

d.abtahi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-04, 1401/11/15

##### Expected recruitment end date

2023-05-05, 1402/02/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

A randomized study to compare the sensory levels of spinal anesthesia for elective cesarean section using crystalloid versus Voluven solution

**Public title**

Comparison of crystalloid with colloid in sensory level induced by spinal anesthesia in cesarean section

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

singleton pregnancy Elective cesarean section  
Gestational age more than 36 weeks Height more than 150 and less than 175 cm Body mass index less than 35 kg/m<sup>2</sup> Consent to study

**Exclusion criteria:**

Sensitivity to local anesthetics

**Age**

From **18 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is done by permutation blocks using PASS ver 21.0.3 software. This software will obtain a list of random numbers, and each number will be assigned to one of the study groups. The assigned numbers will be written on the card, and each card will be placed in an opaque envelope, sealed, and kept in a drawer. When admitting the patient to the operating room, an anesthesia technician who will not interfere in the next stages of the plan, will randomly pick a card for each patient, and based on that, the patient will be placed in one of the three groups of normal saline, Ringer's or tetrastarch.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

During the admission, the anesthesia technician will determine the patient's group using the numbers of the pre-prepared cards. An anesthesiologist who will not be involved in the later stages of the plan will supervise fluid administration by the group. No one except the technician will be aware of the patient's group until the questionnaire information is completed and the patient leaves the operating room. The anesthesiologist in

charge of the patient, the surgeon, and the patient themselves will not be aware of the study group.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Shahid Beheshti University of Medical Science

**Street address**

Emam Hossein Hospital, Shahid Madani St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Approval date**

2023-01-01, 1401/10/11

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1401.643

**Health conditions studied****1****Description of health condition studied**

Hypotension due to drugs

**ICD-10 code**

I95.2

**ICD-10 code description**

Hypotension due to drugs

**Primary outcomes****1****Description**

The sensory level obtained after spinal anesthesia

**Timepoint**

Every 5 to 30 minutes after spinal anesthesia and then at 60 and 90 minutes

**Method of measurement**

The sensory level will be assessed along the midline of the abdomen from T12 towards the patient's head with a blunt needle

**Secondary outcomes**

## 1

### Description

Hypotension after spinal anesthesia

### Timepoint

Throughout the operation in 5-minute intervals to 30 minutes, then in 10-minute intervals until the end of the operation

### Method of measurement

Standard blood pressure monitoring

## Intervention groups

### 1

#### Description

Intervention group: Normal saline group: Within thirty minutes before spinal anesthesia, the anesthesiologist will inject 10 ml/kg of 0.9% sodium chloride solution intravenously to the patient.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Ringer's group: Within thirty minutes before spinal anesthesia, the anesthesiologist will inject 10 ml/kg of Ringer's solution to the patient intravenously.

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group: Voluven group: Within thirty minutes before spinal anesthesia, the anesthesiologist will inject 5 ml/kg of Voluven solution to the patient intravenously.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hospital Emam Hossein

##### Full name of responsible person

Dariush Abtahi

##### Street address

Shahid Madani St

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Tehran

##### Province

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+98 21 7756 7840

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drdariushabtahi@yahoo.com

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zarghi

##### Street address

Tehran Province, Tehran, Velenjak, 7th Floor, Bldg No.2 SBUMS, Arabi Ave

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##### Province

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##### Phone

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##### Email

Intl\_office@sbmu.ac.ir

##### Web page address

<https://en.sbmu.ac.ir>

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dariush Abtahi

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Dariush Abtahi  
**Position**  
Assistant Professor  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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Shahid Beheshti University of Medical Sciences  
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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

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

All data is potentially shareable after unidentified individuals.

### When the data will become available and for how long

One year after the publication of the article

### To whom data/document is available

All jobs

### Under which criteria data/document could be used

All non-personal patient information (anonymously) can be accessed by contacting the responsible author.

### From where data/document is obtainable

email to: drdariushabtahi@yahoo.com

### What processes are involved for a request to access data/document

Sending email and review by the responsible author.

### Comments