Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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/m2 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
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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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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
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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