Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Warmed versus Room-Temperature Intravenous Fluid Co-loading on Spinal Anesthesia-Induced Hypotension in Elderly Hypertensive Patients Undergoing Orthopedic Surgery

Protocol summary

Study aim

To compare warmed versus room-temperature intravenous fluid co-loading on spinal anesthesia-induced hypotension in elderly hypertensive patients undergoing orthopedic surgery.

Design

Randomized, double-blind, parallel-group clinical trial. Sample size 70 (35 per group). Block randomization with sealed envelopes. Single center.

Settings and conduct

Conducting at Al-Karkh Teaching Hospital, Baghdad, Iraq. Elderly hypertensive patients undergoing elective lower limb orthopedic surgery under spinal anesthesia are enrolled after informed consent and randomized to warmed or room-temperature Ringer's lactate co-loading. Standard monitoring includes electrocardiography, pulse oximetry, and non-invasive blood pressure. Participants, anesthesiologist, outcome assessor, and data analyst are blinded; fluids are prepared by a non-blinded nurse and covered with opaque materials.

Participants/Inclusion and exclusion criteria

Inclusion: age ≥65, hypertension on medication, ASA II/III, elective lower limb orthopedic surgery under spinal anesthesia. Exclusion: severe hyperkalemia, severe hepatic impairment, lactic acidosis, inability to cooperate.

Intervention groups

Group W: Ringer's lactate warmed to 37-38°C. Group R: Ringer's lactate at room temperature (20-24°C). Both co-loaded 10-15 mL/kg over 15-20 minutes after spinal block.

Main outcome variables

Primary: incidence of spinal anesthesia-induced hypotension (systolic blood pressure drop ≥20% or <90 mmHg) within 30-45 minutes. Secondary: number of hypotensive episodes, vasopressor requirement, time to first episode.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210222050463N10**
Registration date: **2026-09-16, 1405/06/25**
Registration timing: **prospective**

Last update: **2026-09-16, 1405/06/25**
Update count: **0**

Registration date

2026-09-16, 1405/06/25

Registrant information

Name

Noushin Sarvi Sarmeidani

Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-01, 1405/07/09

Expected recruitment end date

2027-01-29, 1405/11/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of Warmed versus Room-Temperature Intravenous Fluid Co-loading on Spinal Anesthesia-Induced Hypotension in Elderly Hypertensive Patients Undergoing Orthopedic Surgery

Public title
Warmed IV Fluids to Prevent Low Blood Pressure During Spinal Anesthesia in Elderly Patients with High Blood Pressure Undergoing Orthopedic Surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age 65 years or older. Diagnosis of hypertension with regular use of antihypertensive medications. American Society of Anesthesiologists (ASA) physical status II or III. Candidate for elective lower limb orthopedic surgery (hip or knee) under spinal anesthesia. Absence of significant valvular heart disease, severe heart failure, significant arrhythmias, or recent myocardial infarction. Willingness to participate and provision of written informed consent.

Exclusion criteria:
Severe hyperkalemia. Severe hepatic impairment. Lactic acidosis. Inability to cooperate or complete questionnaires/assessments due to cognitive or communication impairment.

Age
From **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

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

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Method of randomization: Block randomization with a fixed block size determined by the statistician. Unit of randomization: Individual participants. Randomization strata: No stratification was used. Tools used for randomization: Random Allocation software (or a random number table) and sequentially numbered, opaque, sealed envelopes. How the random sequence was built: The randomization sequence was generated in advance by a statistician who was not involved in participant enrollment or data collection. Block randomization was used to ensure balance between the two study groups. Allocation concealment: Yes. The generated allocation sequence was placed in sequentially numbered, opaque, sealed envelopes. These envelopes were opened in order by a research assistant who was not involved in data collection or outcome assessment. The envelopes were opened only after the participant had been enrolled and written informed consent had been obtained.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, the attending anesthesiologist (care provider), the investigator, the outcome assessor, and the data analyst are blinded to group allocation. The intravenous fluids are prepared and coded by a nurse who is not involved in data collection or outcome assessment. The fluid bags and infusion tubing are covered with opaque insulating materials to prevent identification of fluid temperature. Only the nurse responsible for preparing the study fluids is aware of the intervention assignment. The allocation codes are kept confidential until completion of data collection and statistical analysis. The Data and Safety Monitoring Board is not involved in this study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Vice Chancellery for Research and Technology, 1st Floor, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd., Ahvaz

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Approval date
2026-08-28, 1405/06/06

Ethics committee reference number
IR.AJUMS.REC.1405.258

Health conditions studied

1

Description of health condition studied
Spinal anesthesia-induced hypotension in elderly patients

ICD-10 code
I95.9

ICD-10 code description
Hypotension, unspecified

Primary outcomes

1

Description
Incidence of spinal anesthesia-induced hypotension, defined as a decrease in systolic blood pressure of 20 percent or more from baseline or a decrease in systolic blood pressure to less than 90 millimeters of mercury, whichever occurs first.
Timepoint
From the time of spinal block placement up to 45 minutes after the block.
Method of measurement
Non-invasive blood pressure monitoring using an automated oscillometric blood pressure device. Blood pressure is measured at baseline and then every 2 to 4 minutes during the first 20 minutes after spinal block, and every 15 minutes thereafter until 60 minutes after the block or until the end of surgery.

Secondary outcomes

1

Description
Total number of hypotensive episodes, defined as a decrease in systolic blood pressure of 20 percent or more from baseline or a decrease in systolic blood pressure to less than 90 millimeters of mercury, whichever occurs first.
Timepoint
From the time of spinal block placement until 60 minutes after the block or until the end of surgery.
Method of measurement
Non-invasive blood pressure monitoring using an automated oscillometric blood pressure device, recorded every 2 to 4 minutes during the first 20 minutes after spinal block and every 15 minutes thereafter.

2

Description
Time in minutes from spinal block placement to the first occurrence of hypotension.
Timepoint
From the time of spinal block placement until the first hypotensive episode or up to 45 minutes after the block.
Method of measurement
Recording the time from intrathecal injection to the first hypotensive reading, using a stopwatch and non-invasive blood pressure monitoring.

3

Description
Total dose of vasopressor administered to treat hypotension, including ephedrine or phenylephrine.
Timepoint
During surgery, from spinal block placement until the end of surgery.
Method of measurement
Recording the type, dose, frequency, and timing of vasopressor administration from the anesthesia record.

4

Description
Patient satisfaction score with anesthesia and surgery, measured using a Likert scale questionnaire.
Timepoint
In the post-anesthesia care unit after surgery.
Method of measurement
A short patient satisfaction questionnaire with Likert scale responses.

5

Description
Patient comfort score in the post-anesthesia care unit, measured using a Likert scale questionnaire.
Timepoint
In the post-anesthesia care unit after surgery.
Method of measurement
A short patient comfort questionnaire with Likert scale responses.

6

Description
Systolic blood pressure measured at predefined intervals after spinal anesthesia.
Timepoint
At baseline before spinal anesthesia, every 2 to 4 minutes during the first 20 minutes after the block, and every 15 minutes thereafter until 60 minutes after the block or until the end of surgery.
Method of measurement
Non-invasive blood pressure monitoring using an automated oscillometric blood pressure device.

7

Description
Diastolic blood pressure measured at predefined intervals after spinal anesthesia.
Timepoint
At baseline before spinal anesthesia, every 2 to 4 minutes during the first 20 minutes after the block, and every 15 minutes thereafter until 60 minutes after the block or until the end of surgery.
Method of measurement
Non-invasive blood pressure monitoring using an automated oscillometric blood pressure device.

8

Description
Mean arterial pressure measured at predefined intervals after spinal anesthesia.
Timepoint
At baseline before spinal anesthesia, every 2 to 4

minutes during the first 20 minutes after the block, and every 15 minutes thereafter until 60 minutes after the block or until the end of surgery.

Method of measurement

Non-invasive blood pressure monitoring using an automated oscillometric blood pressure device.

9

Description

Heart rate measured at predefined intervals after spinal anesthesia.

Timepoint

At baseline before spinal anesthesia, every 2 to 4 minutes during the first 20 minutes after the block, and every 15 minutes thereafter until 60 minutes after the block or until the end of surgery.

Method of measurement

Continuous electrocardiography monitoring.

10

Description

Peripheral oxygen saturation measured at predefined intervals after spinal anesthesia.

Timepoint

At baseline before spinal anesthesia and continuously during surgery.

Method of measurement

Pulse oximetry.

Intervention groups

1

Description

Intervention group: Warmed intravenous fluid group. Participants receive Ringer's lactate solution (manufactured by Shahid Ghazi Pharmaceutical Co.) warmed to 37-38 degrees Celsius using a BIEGLER BW 685 standard intravenous fluid warming device. The fluid is administered as co-loading immediately after intrathecal injection and establishment of spinal anesthesia. The volume is 10-15 milliliters per kilogram of body weight during the first 15-20 minutes, followed by maintenance fluid at 2-4 milliliters per kilogram per hour.

Category

Prevention

2

Description

Control group: Room-temperature intravenous fluid group. Participants receive the same Ringer's lactate solution (manufactured by Shahid Ghazi Pharmaceutical Co.) at operating room temperature, approximately 20-24 degrees Celsius. The fluid is administered as co-loading immediately after intrathecal injection and establishment of spinal anesthesia. The volume is 10-15 milliliters per kilogram of body weight during the first 15-20 minutes, followed by maintenance fluid at 2-4 milliliters per kilogram per hour.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
Nooshin Sarvi-Sarmeydani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

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

No

Title of funding source

Research team (self-funded)

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Nooshin Sarvi-Sarmeydani

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Anesthesiology

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Position
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Other areas of specialty/work
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Person responsible for updating data

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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
No - There is not a plan to make this available

Analytic Code
Not applicable

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

Title and more details about the data/document
Deidentified individual participant data (IPD), data dictionary, study protocol, statistical analysis plan, and informed consent form. The IPD set includes all collected data on demographics, clinical characteristics, hemodynamic parameters (systolic blood pressure, diastolic blood pressure, mean arterial pressure, heart rate, oxygen saturation), incidence and number of hypotensive episodes, time to first hypotensive episode, vasopressor dose and frequency, and patient satisfaction and comfort scores. All data will be deidentified before sharing. The data dictionary will contain variable names, definitions, coding, and units. The study protocol describes the full methods. The statistical analysis plan describes the planned analyses. The informed consent form is the version approved by the ethics committee.

When the data will become available and for how long

Data will become available 6 months after publication of the primary results and will remain available for 5 years.

To whom data/document is available

Researchers working in academic institutions, research centers, or healthcare organizations. Applicants from the industry may also apply if they provide a methodologically sound proposal.

Under which criteria data/document could be used

Data will be shared for secondary analyses that are methodologically sound and approved by the principal investigator. Requests must include a written proposal describing the research question, analysis plan, and intended use. A signed data access agreement is required. Data may not be used for commercial purposes or to re-identify participants. Requests will be reviewed by the principal investigator and the research team.Data will be shared for secondary analyses that are methodologically sound and approved by the principal investigator. Requests must include a written proposal describing the research question, analysis plan, and intended use. A signed data access agreement is required. Data may not be used for commercial purposes or to re-identify participants. Requests will be reviewed by the principal investigator and the research team.

From where data/document is obtainable

Data and documents are obtainable by contacting the principal investigator: Dr. Ali Khalafi Department of Anesthesia Technology, School of Paramedical Sciences, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran. Email: khalafi-a@ajums.ac.ir Telephone: 09163359407

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

Applicants should send a written request by email to the principal investigator, including a brief research proposal, the intended analysis plan, and the institutional affiliation. The request will be reviewed by the principal investigator and the research team within 4 weeks. If approved, a data access agreement will be sent to the applicant for signature. After the signed agreement is received, the deidentified data and requested documents will be transferred electronically within 2 weeks. The entire process is expected to take approximately 6 to 8 weeks.

Comments