Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of preload and coload of ringer lactate to prevent hypotension during elective cesarean section under spinal anesthesia

Protocol summary

Study aim
Comparison of preload and coload of ringer lactate to prevent hypotension during elective cesarean section under spinal anesthesia

Design
Phase-III single-blind randomized clinical trial on 60 patients, randomization with sealed envelopes

Settings and conduct
This single-blind randomized clinical trial will include 60 women aged 18-45 years with singleton term pregnancies referred to Khalij Fars Hospital, Bandar Abbas for elective cesarean section under spinal anesthesia. Patients will randomly be allocated to two equal groups: the preload group will receive 10 ml/kg Ringer's solution within 15 min before the blockade, while the co-load group will receive this amount of Ringer's during the blockade. Hemodynamic parameters at different time points, maternal complications, and neonatal outcomes will be recorded and compared between groups. The investigator and the outcome assessors will be blinded to the grouping of the patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18-45 years Singleton term pregnancy Elective cesarean section Spinal anesthesia American Society of Anesthesiologists (ASA) class I or II Exclusion criteria: Twin or multiple pregnancy ASA class above II Hypertension or cardiovascular diseases Contraindications of spinal anesthesia Hypersensitivity to bupivacaine Renal disorders Severe hemorrhage during surgery requiring blood transfusion Uterine atony requiring hysterectomy Block failure or incomplete block demanding extra anesthetics

Intervention groups
The preload group will receive 10 ml/kg Ringer's solution within 15 min before the blockade, while the co-load group will receive this amount of Ringer's during the blockade.

Main outcome variables
Hypotension during cesarean section

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110313006044N5**
Registration date: **2022-03-25, 1401/01/05**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-25, 1401/01/05**
Update count: **0**

Registration date
2022-03-25, 1401/01/05

Registrant information

Name
Hashem Jarineshin

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 76 3334 5009

Email address
hjarineshin@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-04-20, 1401/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of preload and coload of ringer lactate to prevent hypotension during elective cesarean section under spinal anesthesia

Public title

Preload versus coload of ringer lactate to prevent hypotension during elective cesarean section under spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-45 years Singleton term pregnancy Elective cesarean section Spinal anesthesia American Society of Anesthesiologists (ASA) class I or II

Exclusion criteria:

Twin or multiple pregnancy ASA class above II Hypertension or cardiovascular diseases Contraindications of spinal anesthesia Hypersensitivity to bupivacaine Renal disorders Severe hemorrhage during surgery requiring blood transfusion Uterine atony requiring hysterectomy Block failure or incomplete block demanding extra anesthetics

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with individuals as units of randomization along with allocation concealment: 60 unclear envelopes and 60 cards with the names of the groups (A, B) will be prepared (30 cards for each group). The cards will be put into the envelopes and the envelopes will be sealed and provided to the investigator. Upon entrance of each patient to the study, the envelopes will be shuffled and one will randomly be selected. The patient will be allocated to group A or B based on the card inside the selected envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the difference in the interventions the participants cannot be blinded. However, the investigator and the outcome assessor will be unaware of patients' interventions.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hormozgan University of Medical Sciences

Street address

Jomhouri Eslami Blvd., Shahid Mohammadi Hospital

City

Bandar Abbas

Province

Hormozgan

Postal code

9791991551

Approval date

2018-07-22, 1397/04/31

Ethics committee reference number

HUMS.REC.1397.170

Health conditions studied

1

Description of health condition studied

Hypotension during cesarean section

ICD-10 code

I95

ICD-10 code description

Hypotension

Primary outcomes

1

Description

Maternal blood pressure

Timepoint

Baseline, immediately after spinal anesthesia, then at 2, 4, 6, 8, 10, 15, 20, 25, 30, 40, 50, and 60 min after spinal anesthesia and in the recovery unit

Method of measurement

Monitoring device

Secondary outcomes

1

Description

Maternal mean arterial pressure

Timepoint

Baseline, immediately after spinal anesthesia, then at 2, 4, 6, 8, 10, 15, 20, 25, 30, 40, 50, and 60 min after spinal anesthesia and in the recovery unit

Method of measurement

Monitoring device

2

Description
Maternal heart rate
Timepoint
Baseline, immediately after spinal anesthesia, then at 2, 4, 6, 8, 10, 15, 20, 25, 30, 40, 50, and 60 min after spinal anesthesia and in the recovery unit
Method of measurement
Monitoring device

3

Description
Maternal oxygen saturation
Timepoint
Baseline, immediately after spinal anesthesia, then at 2, 4, 6, 8, 10, 15, 20, 25, 30, 40, 50, and 60 min after spinal anesthesia and in the recovery unit
Method of measurement
Monitoring device

4

Description
Neonatal Apgar score
Timepoint
1 and 5 min after delivery
Method of measurement
Clinical assessment

Intervention groups

1

Description
Intervention group: Patients in the preload group will receive 10 ml/kg Ringer's solution (Samen Pharmaceutical Co., Mashhad, Iran) within 15 min before the blockade
Category
Prevention

2

Description
Intervention group: Patients in the co-load group will receive 10 ml/kg Ringer's solution (Samen Pharmaceutical Co., Mashhad, Iran) during the blockade
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Khalij Fars Hospital, Bandar Abbas
Full name of responsible person
Hashem Jarineshin
Street address
Pardis Blvd.
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Hormozgan
Postal code
7919783141
Phone
+98 76 3367 0280
Email
hjarineshin@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellery for Research Hormozgan University of Medical Sciences
Full name of responsible person
Teamur Aghamolaei
Street address
Imam Hossein Blvd., across from Kargaran Sports Complex
City
Bandar Abbas
Province
Hormozgan
Postal code
7919693116
Phone
+98 76 3371 0393
Email
teaghamolaei@gmail.com
Web page address
https://resv.hums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellery for Research Hormozgan 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
Bandare-abbas University of Medical Sciences
Full name of responsible person

Hashem Jarineshin

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not 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