

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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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Bandar Abbas

Province

Hormozgan

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7919783141

Phone

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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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Person responsible for scientific inquiries

Contact

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Professor

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Person responsible for updating data

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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