Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A randomized controlled investigation of crystalloid preloading and co-loading for the avoidance of spinal block-related low blood pressure in parturients undergoing cesarean section

Protocol summary

Study aim

The aim of this study is to compare the effectiveness of crystalloid preloading versus crystalloid coloading in reducing the incidence and severity of spinal anesthesia-induced hypotension among women undergoing cesarean section under spinal anesthesia

Design

Randomised, parallel group trial, sample size of 120. Randomisation was 1:1 ratio

Settings and conduct

The study will be conducted as a single-center randomized controlled trial.

Participants/Inclusion and exclusion criteria

inclusion criteria: Term pregnancy (≥37 completed weeks of gestation). Scheduled for cesarean section under spinal anesthesia. Baseline hemodynamically stable before spinal anesthesia. Able to provide written informed consent to participate in the study. exclusion criteria: Patient refusal or inability to provide informed consent. Contraindication to spinal anesthesia or planned general anesthesia. Significant renal disease or impaired renal function. Patients receiving significant intravenous fluid resuscitation before randomization Emergency cesarean section requiring immediate general anesthesia.

Intervention groups

Crystalloid Preloading: Participants will receive intravenous crystalloid solution as a preload before administration of spinal anesthesia. The specified volume and timing will be according to the study protocol. Crystalloid Coloading: Participants will receive intravenous crystalloid solution as a coload, initiated at the time of administration of spinal anesthesia. The specified volume and timing will be according to the study protocol

Main outcome variables

participants developing hypotension after cesarian will be compared between the crystalloid preloading and coloading groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260818070708N1**
Registration date: **2026-08-25, 1405/06/03**
Registration timing: **prospective**

Last update: **2026-08-25, 1405/06/03**
Update count: **0**

Registration date

2026-08-25, 1405/06/03

Registrant information

Name

Faiza shabbir

Name of organization / entity

Lady reading hospital

Country

Pakistan

Phone

+92 333 9136480

Email address

khurramyounas17@yahoo.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-09, 1405/07/17

Expected recruitment end date

2026-12-10, 1405/09/19

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A randomized controlled investigation of crystalloid preloading and co-loading for the avoidance of spinal block-related low blood pressure in parturients undergoing cesarean section

Public title
avoidance of low blood pressure in pregnant women going through cessarean
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Term pregnancy (≥37 completed weeks of gestation) Scheduled for cesarean section under spinal anesthesia Baseline hemodynamically stable before spinal anesthesia. Able to provide written informed consent to participate in the study
Exclusion criteria:
Patient refusal or inability to provide informed consent Contraindication to spinal anesthesia or planned general anesthesia. Emergency cesarean section requiring immediate general anesthesia
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **112**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible participants will be randomized individually in a 1:1 ratio to the crystalloid preloading or crystalloid co-loading group using computer-generated permuted block randomization with variable block sizes of 4 and 6. A random allocation sequence will be generated before commencement of participant recruitment. Sequentially numbered, opaque, sealed envelopes containing the group assignments will be prepared according to the randomization sequence. After confirmation of eligibility and obtaining informed consent, the next sequential envelope will be opened to determine the participant's allocation. Allocation concealment will be maintained until the time of assignment. No stratification will be used..
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Lady reading hospital Institutional review board
Street address
Lady reading hospital, near balahisar fort, Peshawar, Pakistan
City
Peshawar
Postal code
25000
Approval date
2025-05-19, 1404/02/29
Ethics committee reference number
202/LRH/MTI

Health conditions studied

1

Description of health condition studied
TO AVOID LOW BLOOD PRESSURE IN PATIENT AFTER CESAREAN SECTION
ICD-10 code
O74.6
ICD-10 code description
Other complications of spinal and epidural anesthesia during labor and delivery

Primary outcomes

1

Description
stable normal blood pressure
Timepoint
Intraoperative period (from spinal anesthesia until 30 minutes after spinal anesthesia).
Method of measurement
sphygmomonomete

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Crystalloid coloading. Participants will receive an intravenous crystalloid solution at a dose of 10 mL/kg, administered intravenously immediately

after initiation of spinal anesthesia. The crystalloid solution will be infused over approximately 20 minutes. The infusion will be initiated immediately after spinal anesthesia and continued for 20 minutes, according to the predefined study protocol. No additional study-specific fluid intervention will be administered. The type, concentration, brand, and manufacturer of the crystalloid solution used will be documented at the time of administration.

Category

Treatment - Other

2

Description

Control group: Crystalloid preloading. Participants will receive an intravenous crystalloid solution at a dose of 10 mL/kg, administered intravenously 20 minutes before initiation of spinal anesthesia. The crystalloid solution will be infused over approximately 20 minutes using an intravenous infusion, according to the predefined study protocol. No additional study-specific fluid intervention will be administered. The type, concentration, brand, and manufacturer of the crystalloid solution used will be documented at the time of administration.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Lady reading hospital

Full name of responsible person
Roheena Wadud

Street address
Lady reading hospital, near balahisar fort, Peshawar, Pakistan

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Peshawar

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25000

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+92 345 9192727

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khurranyounas17@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Lady reading hospital

Full name of responsible person
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roheena.wadud@lrh.edu.pk

Grant name

Grant code / Reference number

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

Title of funding source
Lady reading hospital

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
lady reading hospital

Full name of responsible person
Faiza Shabbir

Position
trainee medical officer

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Faiza Shabbir

Position

Trainee medical officer / resident doctor

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

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

Title and more details about the data/document
IPD collected for the primary outcome measure only

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
only available for people working in academic institutions

Under which criteria data/document could be used
Data and documents may be used for legitimate scientific and academic research purposes, subject to applicable ethical requirements, institutional policies, and protection of participant confidentiality

From where data/document is obtainable
The requested documents will be obtainable from the principal investigator upon reasonable request.

What processes are involved for a request to access data/document
Requests may be submitted by email to the contact person listed in the IRCT registration and will be considered subject to applicable ethical, institutional, and confidentiality requirements

Comments