

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 coload 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 Coload: 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 coload 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

Not yet 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 cesarean

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

sphygmomanomete

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Crystalloid coloadng. 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

City

Peshawar

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Phone

+92 345 9192727

Email

khurramyounas17@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Lady reading hospital

Full name of responsible person

Roheena Wadud

Street address

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Phone

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Email

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

Street address

lady reading hospital, near balahisar fort, peshawar, pakistan

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Lady reading hospital

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

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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