

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the effect of intravenous fluid therapy before spinal anesthesia on the occurrence of headache and hemodynamic disorders in caesarean section candidates referred to Amiralmomenin Hospital in 2023-2024

Protocol summary

Study aim

Effect of pre-spinal anesthesia intravenous fluid therapy on the incidence of post-dural puncture headache and hemodynamic disturbances in cesarean section patients

Design

- Type: Single-blind randomized controlled trial (RCT)
- Groups: Two groups (Intervention vs. Control)
- Randomization: Block randomization or random table method
- Blinding: Patients are blinded to group assignment. IV fluids are prepared in identical, coded bags. The anesthesiologist and outcome assessors are also blinded to group allocation.

Settings and conduct

- Setting: Amir-al-Momenin Hospital, labor ward and operating room
- Methods: Patients are evaluated preoperatively and provide informed consent
- Intervention group: receives IV crystalloid [10–15 ml/kg] prior to spinal anesthesia
- Control group: receives fluids only as clinically indicated
- Outcomes: Hemodynamic parameters recorded in the operating room; post-dural puncture headache assessed at 24, 48 hours, and day 3 postoperatively

Participants/Inclusion and exclusion criteria

- Pregnant women scheduled for cesarean section, aged 18–45 years
- ASA physical status I–II
- Provided informed consent for participation

Intervention groups

1. Intervention group: Receive intravenous crystalloid [10–15 ml/kg] over 15–20 minutes before spinal anesthesia.
2. Control group: No prophylactic preloading; fluids are given only as clinically indicated.

Main outcome variables

- Primary outcome: Incidence of PDPH at 24, 48 hours, and day 3 postoperatively, assessed by patient report and VAS (0–10).
- Secondary outcome: Hemodynamic disturbances, defined as $\geq 20\%$ drop in systolic BP or

MAP < 65 mmHg, and requirement for vasopressors, recorded intraoperatively.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240904062951N1**

Registration date: **2025-08-22, 1404/05/31**

Registration timing: **retrospective**

Last update: **2025-08-22, 1404/05/31**

Update count: **0**

Registration date

2025-08-22, 1404/05/31

Registrant information

Name

Pourya Cheraghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 932 5873

Email address

ccp41519@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-23, 1404/05/01

Expected recruitment end date

2025-08-16, 1404/05/25

Actual recruitment start date

2025-07-23, 1404/05/01
Actual recruitment end date
 2025-08-16, 1404/05/25
Trial completion date
 2025-08-16, 1404/05/25

Scientific title
 Investigating the effect of intravenous fluid therapy before spinal anesthesia on the occurrence of headache and hemodynamic disorders in caesarean section candidates referred to Amiralmomenin Hospital in 2023-2024

Public title
 Investigating the effect of fluid infusion before spinal anesthesia on headache and low blood pressure after cesarean section

Purpose
 Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Candidates for cesarean section under spinal anesthesia
 Informed consent to participate in the study
Exclusion criteria:

Age
 From **16 years** old to **50 years** old

Gender
 Female

Phase
 2-3

Groups that have been masked

- Participant

Sample size
 Target sample size: **120**
 Actual sample size reached: **120**

Randomization (investigator's opinion)
 N/A

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description
 The study is designed as single-blind. Patients will be unaware of their allocation to the intervention group (receiving intravenous fluid therapy before spinal anesthesia) or the control group. Intravenous fluids will be prepared in identical bags and coded by the anesthesia nurse. The anesthesiologist in charge and the outcome assessors (evaluating headache and hemodynamic changes after surgery) will remain blinded to the group allocation. The allocation code will be kept confidential until the end of data collection.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Tehran

Street address

Shariati st, Attari Moghadam st

City

Tehran

Province

Tehran

Postal code

1949635881

Approval date

2024-09-04, 1403/06/14

Ethics committee reference number

IR.IAU.TMU.REC.1403.228

Health conditions studied

1

Description of health condition studied

headache and hemodynamic disorders

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Incidence of post-dural puncture headache (PDPH) at 24, 48 hours, and days 3 and 7 postoperatively, assessed by patient report and pain intensity using the VAS scale (0-10). Hemodynamic disturbances, defined as systolic blood pressure decrease $\geq 20\%$ from baseline, MAP < 65 mmHg, or requirement for vasopressors, recorded intraoperatively.

Timepoint

Hemodynamic parameters: baseline blood pressure and heart rate measured before spinal block. • Post-dural puncture headache (PDPH): assessed at 24 hours, 48 hours, and on day 3 postoperatively

Method of measurement

Hemodynamic disturbances: Blood pressure and heart rate are recorded using the operating room monitor. A decrease $\geq 20\%$ from baseline or MAP < 65 mmHg is considered hemodynamic disturbance. The need for vasopressors is also recorded. Post-dural puncture headache (PDPH): Assessed by patient report and pain intensity using the VAS scale (0-10).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Preloading with intravenous crystalloid (e.g., Ringer's lactate/normal saline) at [10-15 ml/kg, max 1000 ml] over [15-20 minutes], administered immediately before spinal anesthesia. Fluids are prepared in identical, coded bags. All other anesthetic management follows routine institutional protocol.

Category

Prevention

2

Description

Control group: Patients in this group will receive 250 mL of intravenous crystalloid (Ringer's lactate or normal saline) immediately before spinal anesthesia. The infusion will be administered over 15-20 minutes. The fluid bags will be prepared in identical, coded form to maintain blinding. All other anesthetic management will be performed according to the routine departmental protocol.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir almomnin hospital

Full name of responsible person

Pourya cheraghi

Street address

Nastaran street

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1811694784

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Islamic azad university

Street address

Nastaran street

City

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Email

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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

Islamic azad university

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

Islamic Azad University

Full name of responsible person

Pourya cheraghi

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Pourya

Position

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Latest degree

A Level or less

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

A Level or less

Other areas of specialty/work

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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

Patient Privacy

Study Protocol

Undecided - It is not yet known if there will be 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

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

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

Title and more details about the data/document

Effect of pre-spinal anesthesia intravenous fluid therapy on the incidence of post-dural puncture headache and hemodynamic disturbances in cesarean section patients at Amir-al-Momenin Hospital, 2023-2024

When the data will become available and for how long

Data collection period: From the start of patient enrollment at the hospital (2023) until the completion of follow-up on day 3 postoperatively for the last patient (2024)

To whom data/document is available

- The main research team, including the principal investigator, anesthesiologist, and trained nurse
- Statistician or data analyst responsible for data processing and analysis

Under which criteria data/document could be used

- The main research team, including the principal investigator, anesthesiologist, and trained nurse
- Statistician or data analyst responsible for data processing and analysis

From where data/document is obtainable

Principal Investigator

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

Submission of written request: The applicant must submit a written request to the Principal Investigator or the hospital research office, specifying the scientific/research purpose, type of data required, and duration of use.

Comments