# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Investigating the effect of intravenous fluid therapy before spinal anesthesia on theoccurrence of headache and hemodynamic disorders in caesarean section candidatesreferred 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 ≥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 theoccurrence of headache and hemodynamic disorders in caesarean section candidatesreferred 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 coomittee 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 ≥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 ≥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

**City**
Tehran

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**Postal code**
1811694784

**Phone**
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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Islamic Azad University

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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

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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**
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**