Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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1811694784

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
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

Contact

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Islamic Azad University

Full name of responsible person
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Position
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Latest degree
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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