Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of aminophylline and paracetamol for the prevention of post-dural puncture headache in women undergoing cesarean section under spinal anesthesia: A randomized controlled trial

Protocol summary

Study aim

Comparison of aminophylline and paracetamol for the prevention of post-dural puncture headache in women undergoing cesarean section under spinal anesthesia

Design

This controlled, parallel-group, double-blinded, randomized phase 3 trial will include 100 women. Randomization will use computer-generated block sequences with allocation concealment.

Settings and conduct

The study will be conducted at Al-Habobi Hospital, Nasiriyah, Iraq. Participants and outcome assessor will be blinded to group allocation. The intervention group will receive intravenous aminophylline, and the control group will receive intravenous paracetamol. All participants will receive standardized care and will be followed daily for five days after spinal anesthesia.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women aged 18-45 years, candidate for elective cesarean delivery, ASA I-II, singleton pregnancy, eligible for spinal anesthesia, and successful spinal anesthesia achieved on the first needle insertion. Exclusion criteria: History of headache or post-dural puncture headache, contraindications to spinal anesthesia, spinal abnormalities, multiple pregnancy, BMI >40 kg/m², failed spinal anesthesia, neurological disorders, hypersensitivity to study drugs, or significant cardiovascular or seizure disorders.

Intervention groups

All participants will receive standardized perioperative care, and spinal anesthesia will be administered according to the institutional protocol. Participants will then be randomly assigned to one of two groups. Group A will receive intravenous aminophylline, and Group B will receive intravenous paracetamol.

Main outcome variables

Primary outcome: Incidence of post-dural puncture headache within five days. Secondary outcomes: Post-dural puncture headache severity, onset time of post-dural puncture headache, and drug-related adverse effects within five days.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130803014251N13**
Registration date: **2026-07-15, 1405/04/24**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-15, 1405/04/24**
Update count: **0**

Registration date

2026-07-15, 1405/04/24

Registrant information

Name

MORTEZA NASIRI

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 77 2622 5292

Email address

nasiri.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-13, 1405/04/22

Expected recruitment end date

2026-10-02, 1405/07/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of aminophylline and paracetamol for the prevention of post-dural puncture headache in women undergoing cesarean section under spinal anesthesia: A randomized controlled trial

Public title
Comparison of aminophylline and paracetamol for the prevention of post-spinal anesthesia headache
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women aged 18-45 years Candidate for elective cesarean delivery American Society of Anaesthesiologists (ASA) grade I or II Singleton pregnancy Eligible for spinal anesthesia Successful spinal anesthesia on first needle insertion
Exclusion criteria:
Any history of post-dural puncture headache History of chronic or recurrent headache disorders within the past six months (e.g., migraine or tension-type headache) Contraindications to neuraxial anesthesia (e.g., coagulopathy, soft tissue infections at the needle insertion site, or severe hypovolemia) Spinal deformity or previous spinal surgery Multiple pregnancy Body mass index greater than 40 kilograms per square meter Failed spinal anesthesia requiring conversion to general anesthesia Known neurological disorders (e.g., seizures) Hypersensitivity or contraindication to aminophylline or paracetamol Cardiac arrhythmias, uncontrolled hypertension, or seizure disorders
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly assigned in a 1:1 allocation ratio using a computer-generated randomization sequence. Permuted block randomization with a fixed block size of 4 will be used to ensure balanced allocation between the two study groups. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes, which will be opened only after confirmation of participant eligibility and successful spinal anesthesia.
Blinding (investigator's opinion)
Double blinded
Blinding description
Both participants and anesthesiologist administering the study medications will be blinded to group allocation. Study drugs will be prepared by an independent nurse or pharmacist not involved in patient management or outcome assessment. Aminophylline and paracetamol will be diluted with normal saline to identical volumes and presented in identical, opaque, coded syringes. Allocation codes will be kept securely by the independent drug preparer and will not be revealed until completion of data analysis, unless unblinding is required for patient safety. Outcome assessor will remain blinded throughout the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Public Health & Allied Medical Sciences of Tehran University
Street address
Building of Health School of Tehran University of Medical Sciences, Poursina Alley, Ghods Street, Enghelab Street, Tehran Province, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417744361
Approval date
2026-07-12, 1405/04/21
Ethics committee reference number
IR.TUMS.SPH.REC.1405.120

Health conditions studied

1

Description of health condition studied
Post-dural puncture headache
ICD-10 code
G97.1
ICD-10 code description
Other reaction to spinal and lumbar puncture

Primary outcomes

1

Description
Incidence of post-dural puncture headache
Timepoint
Each patient will be evaluated daily for five consecutive days after the C/S, either in person or via telephone follow-up.
Method of measurement
International Classification of Headache Disorders (ICHD) criteria

Secondary outcomes

1

Description
Severity of post-dural puncture headache
Timepoint
Each patient will be evaluated daily for five consecutive days after the C/S, either in person or via telephone follow-up.
Method of measurement
Visual Analog Scale

2

Description
Onset time of post-dural puncture headache
Timepoint
Each patient will be evaluated daily for five consecutive days after the C/S, either in person or via telephone follow-up.
Method of measurement
A structured postoperative follow-up form

3

Description
Adverse effects of the intervention
Timepoint
Each patient will be evaluated daily for five consecutive days after the C/S, either in person or via telephone follow-up.
Method of measurement
A structured postoperative follow-up form

Intervention groups

1

Description
Intervention group: This group will receive 250 mg of intravenous aminophylline diluted in 150 mL of 0.9% normal saline, administered immediately after delivery of the neonate and repeated at 1, 4, 8, 12, and 24 hours postoperatively.
Category
Prevention

2

Description
Control group: This group will receive 1 g of intravenous paracetamol diluted in 100 mL of 0.9% normal saline, administered immediately after delivery of the neonate and repeated at 1, 4, 8, 12, and 24 hours postoperatively.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Habobi Hospital
Full name of responsible person
Saja Amjed Shlaka Shlaka
Street address
Al-Habobi Street, Nasiriyah, Dhi Qar Governorate, Iraq
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64001–64199
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Email
info@moh.gov.iq

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Nabi Shariati Far
Street address
Tehran University of Medical Sciences, Central Headquarters, Corner of Ghods Street, Keshavarz Boulevard, Tehran, Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
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
Tehran University of Medical Sciences

Full name of responsible person
Dr. Morteza Nasiri

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Only a part of patients' demographical data and main outcomes will be shared.

When the data will become available and for how long
After the publishing of the results

To whom data/document is available

Data will be available only for researchers working on academic and university associations.

Under which criteria data/document could be used

Mention of study details and authors name

From where data/document is obtainable

Dr. Morteza Nasiri: Department of Operating Room, School of Allied Medical Sciences, Tehran University of Medical Sciences, Tehran, Iran

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

Information will provide via the following email upon request. Mortezanasiri.or87@yahoo.com

Comments