Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of intravenous caffeine, dexamethasone and aminophylline injection on headache after spinal anesthesia in patients undergoing section surgery

Protocol summary

Study aim

To determine and compare the effects of intravenous caffeine, dexamethasone, and aminophylline on the prevention of post–spinal anesthesia headache in patients undergoing cesarean section.

Design

This randomized clinical trial uses block randomization to assign eligible cesarean section patients to four groups. Outcomes are compared to evaluate each drug's effectiveness in preventing post-spinal anesthesia headache.

Settings and conduct

The study at Imam Sajjad Hospital will randomly assign cesarean patients to four groups, administer interventions after delivery, and assess headache 24 hours later using VAS.

Participants/Inclusion and exclusion criteria

Inclusion criteria: no prior history of spinal anesthesia or post-dural puncture headache; spinal anesthesia performed by an anesthesiologist using the same needle size and with only one puncture attempt. No personal history of migraine headaches. No contraindications to the study medications. Candidates for elective cesarean section under spinal anesthesia at Imam Sajjad Hospital, Yasuj. Exclusion criteria: known allergy or contraindication to any of the study medications. Use of additional oral or injectable analgesics during the study period. Presence of headache prior to the surgery. Withdrawal from participation or unwillingness to continue cooperation.

Intervention groups

Control group: Intravenous placebo (distilled water) after delivery and placental separation.Caffeine group: Intravenous caffeine 500 mg in 500 mL normal saline, administered after delivery; second dose after 12 hours with monitoring for tachycardia and arrhythmia. Dexamethasone group: Single 8 mg intravenous dexamethasone after delivery. Aminophylline group: Intravenous aminophylline at 0.4 mg/kg/hour after delivery.

Main outcome variables

Post-spinal anesthesia headache severity measured using the 0–10 Visual Analogue Scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251121068066N6**
Registration date: **2025-12-27, 1404/10/06**
Registration timing: **retrospective**

Last update: **2025-12-27, 1404/10/06**
Update count: **0**

Registration date

2025-12-27, 1404/10/06

Registrant information

Name

Atiyeh Hesari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 718 4680

Email address

articlelab2025ir@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-22, 1404/03/01

Expected recruitment end date

2025-07-21, 1404/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of intravenous caffeine, dexamethasone and aminophylline injection on headache after spinal anesthesia in patients undergoing section surgery

Public title

Comparison of the effect of intravenous caffeine, dexamethasone and aminophylline injection on headache after spinal anesthesia in patients undergoing section surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

No prior history of spinal anesthesia or post-dural puncture headache (PDPH). Spinal anesthesia performed by an anesthesiologist using the same needle size and with only one puncture attempt. No history of migraine headaches. No contraindications to the study medications (caffeine, dexamethasone, or aminophylline). Patients undergoing cesarean section with spinal anesthesia at Imam Sajjad Hospital in Yasuj.

Exclusion criteria:

Known allergy or contraindication to any of the study medications. Use of additional oral or injectable analgesics during the study period. Presence of headache prior to the surgery. Withdrawal from participation or unwillingness to continue cooperation.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed using block randomization to ensure balanced allocation across the four study groups. After obtaining written informed consent at the entrance to the operating room, eligible patients were randomly assigned to one of the four groups (control/placebo, caffeine, dexamethasone, or aminophylline). Fixed blocks of four were used, with each group appearing once in each block. The allocation order within each block was determined using a random number table, and this process continued until equal group sizes (35 participants per group) were achieved.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences Headquarters,Shahid Motahari Blvd, Yasuj

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

94799-75919

Approval date

2021-03-17, 1399/12/27

Ethics committee reference number

IR.YUMS.REC.1400.118

Health conditions studied

1

Description of health condition studied

Headache

ICD-10 code

G44.4

ICD-10 code description

Drug-induced headache, not elsewhere classified

Primary outcomes

1

Description

Post-spinal anesthesia headache severity measured using the 0–10 cm Visual Analogue Scale (VAS), where 0 indicates no pain and 10 indicates worst pain. Pain intensity is categorized as mild (1–3), moderate (4–7), or severe (8–10).

Timepoint

24 hours after surgery.

Method of measurement

Measurement method: Headache intensity is assessed using a 10-cm Visual Analogue Scale (VAS), where the patient marks their pain level. Scores are recorded by the researcher.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Caffeine Group: Participants receive intravenous caffeine at a dose of 500 mg diluted in 500 mL normal saline, administered immediately after delivery and placental separation. A second dose is administered 12 hours later. Patients are monitored for potential adverse effects, including tachycardia and cardiac arrhythmias.
Category
Prevention

2

Description
Intervention group: Dexamethasone Group: Participants receive a single intravenous dose of 8 mg dexamethasone immediately after delivery and placental separation.
Category
Prevention

3

Description
Intervention group: Aminophylline Group:Participants receive intravenous aminophylline at a dose of 0.4 mg/kg/hour, initiated immediately after delivery and placental separation.
Category
Prevention

4

Description
Control group: Participants receive a placebo consisting of distilled water administered intravenously immediately after delivery of the newborn and placental separation.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Operating room and ward of Imam Sajjad (AS) Hospital in Yasuj
Full name of responsible person
Ameneh Moeinzadeh
Street address
Imam Sajjad Hospital,Park Saheli,Yasuj
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
75 9174 1413
Phone
+98 74 3333 7001
Email
emamsajad@yums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Dr. Sirous Saleh Nasab
Street address
Vice President for Research and Technology,Yasuj University of Medical Sciences Headquarters, Shahid Motahari Blvd. (RAH),Yasuj
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Province
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Postal code
ندارد
Phone
+98 74 3334 6078
Email
research@yums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj University of Medical Sciences
Proportion provided by this source
50
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
Shahid Beheshti Hospital, Yasuj
Full name of responsible person
Akvan Paymard
Position
Nurse
Latest degree
Master
Other areas of specialty/work

Nursery

Street address
Shahid Dr. Beheshti Hospital, Shahid Mohammad Montazeri Street

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

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

Clinical Study Report
Undecided - It is not yet known if there will be 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