Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of intravenous aminophylline on preventing post-dural puncture headache (PDPH) following spinal anesthesia for elective orthopedic surgeries, a clinical trial

Protocol summary

Study aim

Determining the effect of intravenous aminophylline in preventing headache caused by dural perforation following spinal anesthesia in elective orthopedic surgeries.

Design

This is a two-group, double-blind, randomized clinical trial study conducted on 132 eligible patients using sealed envelopes for randomization.

Settings and conduct

This study is conducted in the field of reducing and controlling headache following spinal anesthesia at Babol University of Medical Sciences and after obtaining informed consent from patients. Blinding of participants and outcome monitors is done using sealed envelopes and group numbering.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients requiring elective orthopedic surgery with spinal anesthesia, having stable vital signs for the spinal anesthesia process (ASA class I and II); age range 15-75 years; and having informed consent to participate in the study. Exclusion criteria: presence of coagulation problems; presence of chronic heart and lung disease; presence of chronic liver disease; presence of allergy to specific drugs; especially anesthetic drugs; history of seizures; and presence of history of use of various opioids.

Intervention groups

For patients in the intervention group, 10 mg of marcaine is injected into the L3-L4 or L4-L5 space, and after anesthesia is stabilized, aminophylline 1 mg/kg in 100 cc of normal saline is infused with cardiac monitoring. For patients in the control group, 10 mg of marcaine is injected into the L3-L4 or L4-L5 space, and after anesthesia is stabilized, only 100 cc of normal saline is infused with cardiac monitoring.

Main outcome variables

Measuring the time of headache onset; measuring headache severity; and measuring the duration of headache

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221227056940N3**
Registration date: **2025-09-26, 1404/07/04**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-26, 1404/07/04**
Update count: **0**

Registration date

2025-09-26, 1404/07/04

Registrant information

Name
Sina Sohrabi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 17 3262 7824
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sohrabi.s@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-06, 1404/06/15

Expected recruitment end date

2026-03-06, 1404/12/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of intravenous aminophylline on preventing post-dural puncture headache (PDPH) following spinal anesthesia for elective orthopedic surgeries, a clinical trial

Public title
The effect of intravenous aminophylline in preventing headache caused by spinal anesthesia in orthopedic surgeries
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients requiring elective orthopedic surgery with spinal anesthesia; Having stable vital signs for the spinal anesthesia procedure (ASA class I and II); Age range 15-75 years; Having informed consent to participate in the research.
Exclusion criteria:
Presence of coagulation problems; Presence of chronic heart and lung disease; Presence of chronic liver disease; Presence of allergies to certain drugs, especially anesthetic drugs; History of seizures; Presence of history of use of various opioids.
Age
From **15 years** old to **75 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **132**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: use block. Random unit: individual. Randomization tool: An online randomization website. Sequence building: using block randomization method with block size of 4. Concealing method: using closed and opaque envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, patient, clinical evaluator and analyzer are blinded. The allocation of patients into two groups A and B is done by a qualified nurse who has no aware of the actions performed in the two groups. Clinical examination and outcome evaluation will be record by a qualified nurse without any information about the type of intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Babol University of Medical Sciences
Street address
Babol University of Medical Sciences; Ganj Afroz St.; Babol; Mazandaran
City
Babol
Province
Mazandaran
Postal code
۴۷۱۷۶-۴۷۷۴۵
Approval date
2025-06-30, 1404/04/09
Ethics committee reference number
IR.MUBABOL.REC.1404.074

Health conditions studied

1

Description of health condition studied
Headache following spinal anesthesia for elective orthopedic surgery
ICD-10 code
T84
ICD-10 code description
Complications of internal orthopedic prosthetic devices, implants and grafts

Primary outcomes

1

Description
Measuring the time of headache onset
Timepoint
At the beginning of the study, one, six, 24 and 48 hours after the patient's full recovery
Method of measurement
Questioning the patient with time control

2

Description
Measuring headache severity
Timepoint
At the beginning of the study, one, six, 24 and 48 hours

after the patient's full recovery

Method of measurement

Visual Analog Scale (VAS)

3

Description

Measuring the duration of headache

Timepoint

At the beginning of the study, one, six, 24 and 48 hours after the patient's full recovery

Method of measurement

Questioning the patient with time control

Secondary outcomes

1

Description

Measuring the need for additional analgesic

Timepoint

At the beginning of the study, one, six, 24 and 48 hours after the patient's full recovery

Method of measurement

Questioning the patient and recording the prescribed medication

Intervention groups

1

Description

Intervention group: For patients in the intervention group, 10 mg of marcaine will be injected into the L3-L4 or L4-L5 space, and after anesthesia is stabilized, aminophylline 1 mg/kg in 100 cc of normal saline will be infused with cardiac monitoring.

Category

Treatment - Surgery

2

Description

Control group: For patients in the control group, 10 mg of marcaine will be injected into the L3-L4 or L4-L5 space, and after anesthesia is stabilized, only 100 cc of normal saline will be administered along with cardiac monitoring.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Dr. Sedighe Hasani

Street address

Ayatollah Rouhani Hospital; Ganj Afroz Street; University Square.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Mehdi Rajabnia

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Research Vice-Chancellor of Babol University of Medical Sciences, Ganj Afrooz St.

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person
Dr. Sedighe Hasani
Position
Anesthesia resident
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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