Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of single dose prophylactic intravenous Aminophylline on prevention of postoperative shivering following lower limb orthopedic surgeries under spinal anaesthesia.

Protocol summary

Study aim
The effect of single dose prophylactic intravenous Aminophylline on prevention of postoperative shivering following lower limb orthopedic surgeries under spinal anesthesia

Design
Two arm parallel group randomized trial with 30 patients in each group, randomized with block randomization method

Settings and conduct
This study will be performed in labor ward , Madani hospital, Karj on all participants lower limb orthopedic surgeries under spinal anesthesia who are eligible for the study. Patients who have consciously signed a consent form to participate in the project will be randomly assigned to two groups. The randomization list will be prepared by the statistician. Treatments will be placed in sealed envelopes and will be kept by the out-of-study nurse. After identification of the eligibility of the patient, the procedure will be explained to her and informed consent will be obtained ,completing the final information is the responsibility of the person who is unaware of the type of treatment. The statistician will also be blind.

Participants/Inclusion and exclusion criteria
exclusion criteria: Contraindications to spinal anesthesia, Surgery duration more than 90 minutes, Bleeding more than 0.5 liters, Sensitivity to aminophylline, Taking drugs that interfere with aminophylline, Tachycardia greater than 110 beats per minute or history of arrhythmia prior to injection, Inclusion criteria: Patients with PS ASA grade 1, BMI 19 to 26 ,Having a full fast , Candidate for lower limb orthopedic surgery under spinal anesthesia

Intervention groups
Intervention group: Patients receive intravenously 1.5 mg / kg aminophylline in 100 cc of normal saline . Control group: Patients receive intravenously normal saline

Main outcome variables
Shivering, body temperature, vital signs

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211107052990N1**
Registration date: **2021-12-08, 1400/09/17**
Registration timing: **prospective**

Last update: **2021-12-08, 1400/09/17**
Update count: **0**

Registration date
2021-12-08, 1400/09/17

Registrant information

Name
Mahtab Dolatabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 26 3220 4276

Email address
mahtab.dolatabadi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-05-22, 1401/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of single dose prophylactic intravenous Aminophylline on prevention of postoperative shivering following lower limb orthopedic surgeries under spinal anaesthesia.

Public title
The effect of single dose prophylactic intravenous Aminophylline on prevention of postoperative shivering following surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with PS ASA grade 1 BMI 19 to 26 Having a full fast Candidate for lower limb orthopedic surgery under spinal anesthesia Age between 20-40 years
Exclusion criteria:
Contraindications to spinal anesthesia Surgery duration more than 90 minutes Bleeding more than 0.5 liters Sensitivity to aminophylline Taking drugs that interfere with aminophylline Tachycardia greater than 110 beats per minute or history of arrhythmia prior to injection History of untreated hyperthyroidism or hypothyroidism Anemia (Hb <12) Extensive burns History of hyperthermia Malignant Receiving blood or cold liquids (<37)
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Our sample size is 60 people, with 30 people in each group. Block randomization method was designed by epidemiologist using STATA version 13 software. The number of blocks considered is 6.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The random allocation list will solely available to the epidemiologist. 60 cards containing sequences of treatments will be written and be placed inside sealed envelopes. A10-digit random code, as the patient’s identification number, will be provided for each packet. When the physician announces the eligibility of a patient, the nurse will provide the physician with the envelope. None of the patients should be aware of the type and process of treatment. Also, the person evaluating the outcomes is a third person who is unaware of the random allocation process and type of treatment. Data analysis will be carried out by a statistician who is aware of all the processes performed
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Alborz University of Medical Sciences
Street address
Ethics committee unit; Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street
City
Karaj
Province
Alborz
Postal code
3149779453
Approval date
2021-11-02, 1400/08/11
Ethics committee reference number
IR.ABZUMS.REC.1400.209

Health conditions studied

1

Description of health condition studied
Shivering after spinal anesthesia
ICD-10 code
ICD-10 code description
sur

Primary outcomes

1

Description
Shivering after spinal anesthesia
Timepoint
After discharge from recovery
Method of measurement
Based on the patient's statement and the doctor's opinion

2

Description
Body temperature
Timepoint
After discharge from recovery
Method of measurement
Temperature

3

Description
Vital Sign
Timepoint
After discharge from recovery
Method of measurement
Heart rate monitor, sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients receive intavenously 1.5 mg / kg Aminophylline Ampul , made by pharmaceutical company, in 100 cc of normal saline .
Category
Prevention

2

Description
Control group: Patients receive intravenously normal saline .
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Madani hospital
Full name of responsible person
Mahtab Dolatabadi
Street address
Karaj, Madani Square, Madani Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Mohammad Nourisepehr
Street address
Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street
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Research@abzums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
Mahtab Dolatabadi
Position
Anesthesiology and ICU resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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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