

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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 anaesthesia

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 anaesthesia 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 anaesthesia, 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 anaesthesia

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 intravenously 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

City

Karaj

Province

Alborz

Postal code

۳۱۴۳۷۴۴۶۹۳

Phone

+98 26 3442 7001

Email

madani.crbu@gmail.com

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

City

Karaj

Province

Alborz

Postal code

3198764653

Phone

+98 26 3464 3705

Email

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

Street address

No. 92, Takhti Ave., Golestan Blvd., Azimie

City

Karaj

Province

Alborz

Postal code

۳۱۵۵۷۳۱۸۹۶

Phone

+98 26 3220 4276

Fax

+98 26 3220 4276

Email

mahtab.dolatabadi@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Mahtab Dolatabadi

Position

Anesthesiology and ICU resident

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Fax

+98 26 3220 4276

Email

mahtab.dolatabadi@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Mahtab Dolatabadi

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mahtab.dolatabadi@gmail.com

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