

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

The effects of Aminophyllin on recovery duration, postoperative shivering and PONV with elective general surgery

Protocol summary

Summary

The aim of this project is determination the effects of Aminophyllin on decrease recovery duration, postoperative shivering and PONV with elective general surgery. It was a randomized, double-blind, clinical trial. After obtaining written informed consent from all patients, 88 patients scheduled for elective general surgery Will enter between 18 to 70 yr of aged with American Society of Anesthesiologists (ASA) physical status I or II. Patients with a history of cardiovascular, pulmonary, or thyroid disease; dysautonomia; fever; aminophylline intake within a day before surgery; and who received transplants will leave from this study. The patients will randomly divided into an aminophylline group (n = 44) and a saline control group (n = 44) using a computer- generated randomization list. For interventioent group 4 mg/ kg aminophylline in 10 mL of saline is diluted and for control group 10 mL of saline is given before surgery. The same way will induct anesthesia. Vital signs, duration of recovery, the degree of shivering in recovery and need to treatment of shivering, nausea and vomiting will be measured and record in recovery and 6, 24 houre after surgery. The same: 0 = not shivering; 1 = not visible muscle activity but piloerection, peripheral vasoconstriction, or both are present (other causes excluded); 2 = muscular activity in only one muscle group; 3 = moderate muscular activity in more than one muscle group but no generalized shaking; 4 = violent muscular activity that involves the whole body. without nausea = 0; mild nausea = 1; moderate nausea = 2; severe nausea= 3being or not vomiting recorded and the results will be analyzed using statistical tests.

General information

Acronym

Aminophyllin on postoperative shivering

IRCT registration information

IRCT registration number: **IRCT2017022631642N1**

Registration date: **2017-02-26, 1395/12/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-02-26, 1395/12/08

Registrant information

Name

Mohadese Esmailnejad

Name of organization / entity

Ardebil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Ardebil University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Aminophyllin on recovery duration, postoperative shivering and PONV with elective general surgery

Public title

The effects of Aminophyllin on recovery duration, postoperative shivering and PONV with elective general surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Patients with a history of cardiovascular, pulmonary, or thyroid disease; dysautonomia; fever; aminophylline intake within a day before surgery; and who received transplant, will leave from this study. All patients will enter referred for elective general surgery to Imam Khomeini hospital in Ardebil.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ardebil University of Medical Sciences

Street address

Ardebil University of Medical Sciences, Daneshgah st.

City

Ardabil

Postal code

53141_56198

Approval date

2016-12-11, 1395/09/21

Ethics committee reference number

IR.ARUMS.REC.1395.91

Health conditions studied**1****Description of health condition studied**

Postoperative shivering

ICD-10 code

T88.5

ICD-10 code description

Other complications of anaesthesia

Primary outcomes**1****Description**

Shivering

Timepoint

At the time of recovery

Method of measurement

Scale: 0 = no shivering; 1 = no visible muscle activity but piloerection, peripheral vasoconstriction, or both are present (other causes excluded); 2 = muscular activity in only one muscle group; 3 = moderate muscular activity in more than one muscle group but no generalized shaking; 4 = violent muscular activity that involves the whole body.

Secondary outcomes**1****Description**

Nausea

Timepoint

At the time of recovery, 6 and 24 hours after surgery.

Method of measurement

Scale: no nausea = 0; mild nausea = 1; moderate nausea = 2; severe nausea = 3

Intervention groups**1****Description**

4 mg kg aminophylline in 10 mL of saline is diluted and infusion before surgery. Vital signs, duration of recovery, the degree of shivering and need to treatment shivering in recovery, nausea in recovery and 6,24 hours after surgery will be measured and recorded.

Category

Treatment - Drugs

2**Description**

Ten mL of saline is given before surgery. Vital signs, duration of recovery, the degree of shivering and need to treatment shivering in recovery, nausea in recovery and 6,24 hours after surgery will be measured and recorded.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital in Ardebil

Full name of responsible person

Mohadeseh Esmailnejad

Street address

Ardebil bacij Ave

City

Ardebil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardebil University of Medical Sciences

Full name of responsible person

Dr. Akbar Pirzadeh

Street address

Ardebil University of Medical Sciences, Daneshgah St.

City

Ardebil

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ardebil University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ardebil University of Medical Sciences

Full name of responsible person

Mohadeseh Esmailnejad

Position

Medical student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code
empty

Data Dictionary
empty