

# 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

+98 44 3427 2643

###### Email address

m.esmaeil@arums.ac.ir

##### 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

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Dr. Masod Entezari

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Anesthesiologist

**Other areas of specialty/work**

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## Person responsible for updating data

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**Position**

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**Other areas of specialty/work**

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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*