

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effect of aminophylline on the recovery time of hysterectomy patients under general anesthesia; A randomized double-blind clinical trial

#### Protocol summary

##### Study aim

Determining the effect of aminophylline on the recovery time of patients undergoing hysterectomy with general anesthesia

##### Design

A double-blinded and randomized clinical trial with parallel groups design of 74 patients.

##### Settings and conduct

This study is conducted as a clinical trial in Alzahra Hospital in Rasht. After explaining the purpose and method of the research, informed consent will be obtained. The patient will be in the supine position and standard monitoring will be established. Hydration will begin with normal saline. After pre-oxygenation with 100% oxygen, in case of stable hemodynamics and normal sinus rhythm, anesthesia induction will be performed. All patients will be operated by one anesthesiologist and one surgeon with the same method. After uterus removal by the surgeon, study drugs will be prepared in similar syringes by a technician who is not aware of the study and will be given to the anesthesia assistant. In this study, the anesthesiologist, the anesthesia assistant who records the data and patients are blind. Times of emergence, extubation and recovery will be calculated and compared between the two groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: candidate for hysterectomy under general anesthesia in Alzahra hospital, ASA I, II.

Exclusion criteria: hysterectomy due to malignancy, history of allergy to aminophylline, liver dysfunction, smokers, history of arrhythmia or neurological disorder such as epilepsy

##### Intervention groups

After uterus removal by the surgeon, patients in the intervention group will receive 3 milligrams per kilogram of intravenous aminophylline (manufactured by Caspian

Tamin Pharmaceutical Company) diluted in 100 milliliters of normal saline and the control group will receive the same amount of normal saline in 15 minutes.

##### Main outcome variables

Emergence time, extubation time, recovery time

#### General information

##### Reason for update

The dose and duration of injection of the intervention drug were accidentally entered incorrectly, which got corrected in the updated version.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170314033069N5**

Registration date: **2022-12-31, 1401/10/10**

Registration timing: **prospective**

Last update: **2023-01-09, 1401/10/19**

Update count: **1**

##### Registration date

2022-12-31, 1401/10/10

##### Registrant information

##### Name

Gelare Biazar Biazar

##### Name of organization / entity

Guilan University of Medical Sciences, Alzahra Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3336 9024

##### Email address

biazar@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2023-01-20, 1401/10/30

**Expected recruitment end date**

2024-03-19, 1402/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of aminophylline on the recovery time of hysterectomy patients under general anesthesia; A randomized double-blind clinical trial

**Public title**

The effect of aminophylline on the recovery time of hysterectomy patients under general anesthesia

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

American Society of Anesthesiologists (ASA) I,II  
Candidate for hysterectomy under general anesthesia in Alzahra hospital Women aged 30 to 70

**Exclusion criteria:**

Hysterectomy due to malignancy Any history of allergy to aminophylline or drug components Any dysfunction of the liver, including liver cirrhosis, fatty liver, etc smokers People who have recently received or are taking cimetidine, ciprofloxacin, and macrolides such as erythromycin and clarithromycin History of any type of arrhythmia or neurological disorder such as epilepsy Patient dissatisfaction

**Age**From **30 years** old to **70 years** old**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**Target sample size: **74****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be assigned to two groups A, aminophylline and B control by a random sequence created in blocks of four by WinPepi software, which was created by a statistical consultant and will be performed by a technician who is not aware of the goals of the study.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The drugs will be prepared in similar syringes by the anesthetic technician who is not aware of the goals of the study and will be provided to the anesthesia

assistant. In this study, the anesthesiologist, the anesthesiology assistant who records the patient's information, and the patient are not able to recognize the received intervention, hence the study will be double-blind. In case of any complications, the anesthesiologist present in the operating room will be informed of the treatment groups to take the necessary actions.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Guilan University of Medical Sciences

**Street address**

Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street, Rasht

**City**

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Guilan

**Postal code**

4144654839

**Approval date**

2022-12-07, 1401/09/16

**Ethics committee reference number**

IR.GUMS.REC.1401.464

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

Investigating the effect of aminophylline on the recovery time of patients after hysterectomy

**ICD-10 code**

O74

**ICD-10 code description**

Complications of anesthesia during labor and delivery

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

Emergence from anesthesia

**Timepoint**

From the time of discontinuing administration of anesthetic drugs to the time of patient's eyes getting open after calling her/his name

**Method of measurement**

Time measurement

**2****Description**

Extubation time

**Timepoint**

From the time of discontinuing administration of anesthetic drugs to the time of removing the endotracheal tube

**Method of measurement**

Time measurement

**3****Description**

Recovery time

**Timepoint**

From the time of discontinuing administration of anesthetic drugs to the time of transferring the patient to the ward

**Method of measurement**

Time measurement

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

mean arterial blood pressure (MAP)

**Timepoint**

Before administration of aminophylline and normal saline and then every 5 minutes until transferring to recovery, then every 15 minutes during recovery

**Method of measurement**

Blood pressure measurement with mercury sphygmomanometer

**2****Description**

Heart rate

**Timepoint**

Before administration of aminophylline and normal saline and then every 5 minutes until transferring to recovery, then every 15 minutes during recovery

**Method of measurement**

Heart rate monitor

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

Intervention group: After uterus removal by the surgeon, patients in the intervention group will receive 3 milligrams per kilogram of intravenous aminophylline (manufactured by Caspian Tamin Pharmaceutical Company) diluted in 100 milliliters of normal saline. The infusion will last for 15 minutes.

**Category**

Treatment - Surgery

**2****Description**

Control group: After uterus removal by the surgeon, patients in the control group will receive 100 milliliters of normal saline. The infusion will last for 15 minutes.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Alzahra Hospital

**Full name of responsible person**

Dr Gelareh Biazar

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

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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**

Rasht 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**  
Rasht University of Medical Sciences  
**Full name of responsible person**  
Dr Gelareh Biazar  
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## Person responsible for updating data

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**Other areas of specialty/work**  
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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