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)

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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
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Rasht
Province
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
Street address
Alzahra Hospital,Shahid Siadati Avenue, Namjoo Street,Rasht
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

Position
associate professor, Anesthesiologist

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Research Expert/(MSc) English

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Research Expert

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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