Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effect of Aminophylline (vs. placebo) on the depth of anesthesia and recovery of propofol

Protocol summary

Summary

In a double blinded randomized clinical trial, 154 patients scheduled for lower abdominal surgery (after receiving sufentanil 0.2 mcg/kg, propofol 2.5 mg/kg and atracurium 0.5 mg/kg) are anesthetized and intubated. Patients are in the age of 18-65, ASA I and II, are not pregnant and without prior history of cardiopulmonary and nervous system diseases, with no history of opioids, tranquilizers and theophyline use. Infusion of propofol 200 mcg/kg will be continued. Patients with hypotension which cause decreasing propofol dose or use of vasoactive agents or who needed more opioids during surgery, are excluded. At the end of surgery, infusion of propofol will be hold on after the beginning of spontaneous breathing and in one group aminophyline 1 mg/kg in 10 ml volume with distilled water will be injected intravenously during 2 minutes and in the other group only 10 ml distilled water will be injected. Heart rate, mean arterial blood pressure and oxygen saturation will be recorded every 2 minutes until extubation and then every 5 minutes till release from recovery (by getting at least 8 points from Alderet score). Any other side effects (nausea, vomiting, hypotension, desaturation,...) will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812183520N1**
Registration date: **2011-02-01, 1389/11/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-02-01, 1389/11/12

Registrant information

Name
Bijan Yazdi
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Arak University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2010-12-21, 1389/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Aminophylline (vs. placebo) on the depth of anesthesia and recovery of propofol

Public title

Effect of Aminophylline on the depth of anesthesia and recovery of propofol

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age of 18- 65, ASA I and II, scheduled for lower abdomen surgery, non pregnant, without any history of cardiac, pulmonary and nourologic disease, not using tranquilizers or opioids and theophyline group

drugs. Exclusion criteria: hypotension during anesthesia that do not response to fluid therapy and need to decrease propofol infusion or need for using vasoactive drugs for treatment, need for more opioid during anesthesia.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **154**

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
Arak University of Medical Sciences

Street address
Alam-ol-Hoda st., Shahid Shiroodi Ave.,

City
Arak

Postal code
3819693345

Approval date
2009-12-23, 1388/10/02

Ethics committee reference number
88-68-3

Health conditions studied

1

Description of health condition studied
general anesthesia

ICD-10 code
Y48.2

ICD-10 code description
Other and unspecified general anaesthetics

Primary outcomes

1

Description
recovery time

Timepoint
once

Method of measurement
time from injection of drug or placebo to release from recovery

2

Description
extubation time

Timepoint
once

Method of measurement
time from injection of drug or placebo to extubation

Secondary outcomes

1

Description
oxygen saturation

Timepoint
every 2 minutes from injection of drug or placebo to extubation then every 5 minutes till release from recovery

Method of measurement
pulse oximeter

2

Description
heart rate

Timepoint
every 2 minutes from injection of drug or placebo to extubation then every 5 minutes till release from recovery

Method of measurement
pulse oximeter

3

Description
mean arterial pressure

Timepoint
every 2 minutes from injection of drug or placebo to extubation then every 5 minutes till release from recovery

Method of measurement
automated blood pressure recorder

4

Description
nausea and vomiting

Timepoint
as happens

Method of measurement

diagnosed by anesthetist

5

Description
dysrythmia
Timepoint
as happens
Method of measurement
electrocardiography

Intervention groups

1

Description
Injection of aminophyline, 1 mg/kg in 10 ml of distilled water, at the end of surgery when spontaneous breathing begins and propofol infusion stops.
Category
Prevention

2

Description
Injection of 10 ml of distilled water at the end of surgery when spontaneous breathing begins and propofol infusion stops.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali-e-Asr hospital
Full name of responsible person
Bijan Yazdi M.D
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Department of anesthesia, Vali-e-Asr hospital, Vali - e - asr sq.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Saeed Changizi Ashtiani
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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
Arak 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
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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