

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 theophylline 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 aminophylline 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

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 1222 2003

##### Email address

yazdi@arakmu.ac.ir

#### 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 neurologic disease, not using tranquilizers or opioids and theophylline 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

dysrhythmia

### Timepoint

as happens

### Method of measurement

electrocardiography

## Intervention groups

## 1

### Description

Injection of aminophylline, 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

#### Street address

Department of anesthesia, Vali-e-Asr hospital, Vali - e - asr sq.

#### City

Arak

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

Dr. Saeed Changizi Ashtiani

#### Street address

Pardis Site, Basij sq.

#### City

Arak

### 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

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

Dr. Bijan Yazdi

#### Position

Assistant Professor of anesthesiology

#### Other areas of specialty/work

#### Street address

Department of anesthesia, Vali - e- Asr hospital, Vali - e- Asr sq

#### City

Arak

#### Postal code

#### Phone

+98 86 1222 2003

#### Fax

#### Email

yazdi@arakmu.ac.ir , yazdibijan@hotmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

De. Bijan yazdi

#### Position

Assistant Professor of anesthesiology

#### Other areas of specialty/work

#### Street address

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Bijan Yazdi

**Position**

Assistant Professor of anesthesiology

**Other areas of specialty/work****Street address**

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e- Asr sq

**City**

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**Fax****Email**

yazdi@arakmu.ac.ir , yazdibijan@hotmail.com

**Web page address**

## 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*