

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Evaluation of effect of atropine administration before induction of anesthesia on the incidence of delirium and complications in post-anesthesia care unit among children aged 1-6 years old undergoing lower abdominal surgery as compared with the control group

#### Protocol summary

Delirium; pain; blood pressure; heart rate; percentage of oxygen saturation

#### Study aim

Determining and comparing the effect of atropine administration before induction of anesthesia on the incidence of delirium and complications in post-anesthesia care unit among children aged 1-6 years old undergoing lower abdominal surgery as compared with the control group

#### Design

A randomized, double-blinding clinical trial, with the parallel groups, Phase 2-3 on 70 patients

#### Settings and conduct

In this randomized double-blind randomized clinical trial study, 70 children who are candidates for lower abdominal surgery presented at Imam Hossein Hospital in Isfahan will be included in the study and will be randomly divided into 2 groups. One group will receive atropine and the other group will receive a placebo before induction of anesthesia. Delirium score, pain score, and hemodynamic parameters of patients will be evaluated and compared between the two groups.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: age group of 1 to 6 years old; candidate for lower abdominal surgery; class I and II classification of the American Society of Anesthesiologists, and parental consent to participate in the study. Exclusion criteria: having a child with a psychiatric problem including ADHD and depression, and other behavioral disorders.

#### Intervention groups

Intervention group 1: patients in this group receive 0.02 mg/kg of atropine before induction of anesthesia (after dilution with a volume of 0.1 mg per cc). Control group: patients in this group receive 0.02 mg/kg of normal saline (with the same volume in the first group) before induction of anesthesia.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200825048515N33**

Registration date: **2021-05-13, 1400/02/23**

Registration timing: **prospective**

Last update: **2021-05-13, 1400/02/23**

Update count: **0**

##### Registration date

2021-05-13, 1400/02/23

##### Registrant information

##### Name

Asieh Maghami Mehr

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 0000 0000

##### Email address

asimaghami@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-22, 1400/03/01

##### Expected recruitment end date

2021-09-22, 1400/06/31

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of effect of atropine administration before induction of anesthesia on the incidence of delirium and complications in post-anesthesia care unit among children aged 1-6 years old undergoing lower abdominal surgery as compared with the control group

**Public title**  
Effect of atropine administration before induction of anesthesia on the incidence of delirium and complications in post-anesthesia care unit among children aged 1-6 years old undergoing lower abdominal surgery as compared with the control group

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age category 1 to 6 years old Candidate for lower abdominal surgery Class I and II classification of the American Society of Anesthesiologists Parents' consent to participate in the study  
**Exclusion criteria:**  
Having a child with a psychiatric problem, including ADHD and depression and other behavioral disorders

**Age**  
From **1 year** old to **6 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Data analyser

**Sample size**  
Target sample size: **70**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, 70 eligible patients will be randomly selected. Then, these patients will be randomly encoded using computer software called "Random Allocation" and automatically divided into two groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly assigned to one of the two study groups.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In this study, Placebo and Atropine, are prepared by the pharmacist and placed in coded packages and delivered daily to an anesthesiologist, who prescribes them without knowing the type of each drug. Also, the person recording the patient's clinical information and the

statistical analyst will not be aware of the type of intervention.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Isfahan University of Medical Sciences  
**Street address**  
Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8179964167

**Approval date**  
2017-05-26, 1396/03/05

**Ethics committee reference number**  
IR.MUI.REC.1396.3.855

**Health conditions studied**

**1**

**Description of health condition studied**  
Lower abdomen surgery

**ICD-10 code**  
**ICD-10 code description**

**Primary outcomes**

**1**

**Description**  
Delirium score

**Timepoint**  
Immediately upon entering the recovery ward and 15, 30 and 45 minutes later in the recovery

**Method of measurement**  
Pediatric Anesthesia Emergence Delirium Scale (PAED)

**2**

**Description**  
Pain score

**Timepoint**  
15, 30 and 45 minutes later in the recovery

**Method of measurement**

Behavioral scale derived from the Face, Leg, Activity, Cry, Consolability (FLACC)

### 3

#### **Description**

Blood Pressure

#### **Timepoint**

Immediately after surgery, in the minutes of 15, 30, and 45 during surgery and immediately, 15, 30, and 45 minutes after recovery

#### **Method of measurement**

Monitoring device

### 4

#### **Description**

Heart rate

#### **Timepoint**

Immediately after surgery, in the minutes of 15, 30, and 45 during surgery and immediately, 15, 30, and 45 minutes after recovery

#### **Method of measurement**

Monitoring device

### 5

#### **Description**

Percentage of oxygen saturation

#### **Timepoint**

Immediately after surgery, in the minutes of 15, 30, and 45 during surgery and immediately, 15, 30, and 45 minutes after recovery

#### **Method of measurement**

Monitoring device

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: patients in this group receive 0.02 mg/kg of atropine before induction of anesthesia (after dilution with a volume of 0.1 mg per cc).

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: patients in this group receive 0.02 mg/kg of normal saline (with the same volume in the first group) before induction of anesthesia.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Hossein Hospital in Isfahan

##### **Full name of responsible person**

Amir Shafa

##### **Street address**

Imam Khomeini street

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8195163381

##### **Phone**

+98 31 3386 6266

##### **Email**

shafa\_amir@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Shaghayegh Haghjoo Javanmard

##### **Street address**

Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8174673461

##### **Phone**

+98 31 3668 8597

##### **Email**

dean@med.mui.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

No

#### **Title of funding source**

Isfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Amir Shafa

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Department of Anesthesiology; Al-Zahra Hospital;  
Sofeh boulevard

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**Postal code**

8174675731

**Phone**

+98 31 3620 2020

**Email**

shafa\_amir@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Amir Shafa

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available