

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 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

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Isfahan

Province

Isfahan

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8195163381

Phone

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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.

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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

City

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Province

Isfahan

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Email

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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

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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