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

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

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
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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

Isfehan

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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8195163381
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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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

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Department of Anesthesiology; Al-Zahra Hospital; Sofeh boulevard

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Person responsible for updating data

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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