Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Study of Effect of preoperative oral clonidine on nausea and vomiting after appendectomy surgery in children aged between 3-12 years in Bahrami hospital

Protocol summary

Summary

The aim of this trial is to assess the effect of preoperative oral Clonidine on the incidence of vomiting after appendectomy in children. After signing written informed consent by parents, 60 children, aged 3-12 years, with no contraindication for using study drugs, and scheduled for appendectomy, will be enrolled in this double- blind randomized controlled trial and randomly allocated into two groups. Patients with any history of anti emetic or opioids consumption, during the 24 hours before surgery, or those who need to receive different anesthetic regimen will be excluded. The patients in the intervention group will receive Clonidine, 4µg/kg orally in 20 ml apple juice while in the control group will receive only 20 ml apple juice one hour before anesthesia induction. The anesthetic regimen is similar for both groups. Incidence of vomiting, times of anti emetic drug administration in first 24 hours after surgery, and hemodynamic parameters will be recorded and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011225225N1**
Registration date: **2010-12-24, 1389/10/03**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2010-12-24, 1389/10/03

Registrant information

Name

Seyed mohammad Mireskandari

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2261 8931

Email address

mireskandari@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences and Health Services

Expected recruitment start date

2011-03-01, 1389/12/10

Expected recruitment end date

2011-06-20, 1390/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of Effect of preoperative oral clonidine on nausea and vomiting after appendectomy surgery in children aged between 3-12 years in Bahrami hospital

Public title

Study of Effect of preoperative oral clonidine on nausea and vomiting after appendectomy surgery in children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: informed consent of parents, no contraindication for using study drugs, age 3 to 12 year old, scheduled for appendectomy, no history of motion

sickness, digestive disorders, or other diseases related to nausea and vomiting, ASA class I & II Exclusion criteria: any history of drugs for nausea and vomiting and opioids during the 24 hours before surgery, need for a different anesthetic regimen, time limitation for delivering study drugs before surgery

Age
From **3 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **58**

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
Tehran University of Medical Sciences

Street address
Bahrami Children Hospital, Shaheed Kiaee St, Damavand Ave, Tehran

City
Tehran

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
20083

Health conditions studied

1

Description of health condition studied
Appendicitis

ICD-10 code
K35.9

ICD-10 code description

Primary outcomes

1

Description
Nausea

Timepoint
frequency during the first 24 hours after surgery

Method of measurement
history taking from patient or parents or nurses

2

Description
Vomiting

Timepoint
frequency during the first 24 hours after surgery

Method of measurement
history taking from patient or parents or nurses

3

Description
Need for anti nausea and vomiting drug

Timepoint
frequency of nasea and vomiting during the first 24 hours after surgery

Method of measurement
information taken from patient's records

Secondary outcomes

1

Description
Systolic and diastolic blood pressure

Timepoint
every 10 minutes during surgery and every 2 hours postoperatively

Method of measurement
mannometer

2

Description
heart rate

Timepoint
continuously during surgery and every 2 hours postoperatively

Method of measurement
calculation of pulse rate

Intervention groups

1

Description
Intervention group: Clonidine, 4µg/kg orally in 20 ml apple juice, one hour before anesthesia induction

Category
Treatment - Drugs

2

Description
Control group: 20 ml apple juice, one hour before anesthesia induction
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahrami hospital
Full name of responsible person
Dr Seyed Mohammad Mireskandari
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences and Health Services
Full name of responsible person
Dr Seyed Mohammad Mireskandari
Street address
Bahrami Children Hospital, Shaheed Kiaee St, Damavand Ave, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences and Health Services
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences and Health Services
Full name of responsible person
Dr Seyed Mohammad Mireskandari
Position
Assistant professor of anesthesia department
Other areas of specialty/work
Street address
Bahrami Children Hospital, Shaheed Kiaee St, Damavand Ave, Tehran
City
Tehran
Postal code
Phone
+98 21 6119 2386
Fax
Email
mireskandari@sina.tums.ac.ir
Web page address

Person responsible for updating data

Contact

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