Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation the effect of intravenous paracetamol on post operative pain and nausea and vomiting in pediatric patients undergoing strabismus surgery

Protocol summary

Summary

We are going to assess the effect of intravenous paracetamol on postoperative nausea and vomiting during the first 24 hr after strabismus surgery in pediatric patients aged between 2-12 years in Farabi hospital. After approval by the University Research Ethics Committee and obtaining written informed consent from the parents, 120 children scheduled for strabismus surgery under general anesthesia will be included in this prospective, randomized, double-blind clinical study. Children with hepatic or renal failure, allergy to study drugs, history of motion sickness, previous severe postoperative nausea and vomiting and current use of antiemetic drugs will be excluded from the study. Age, sex, weight and height will be recorded. Induction of general anesthesia will be done with fentanyl 1µ/kg, sodium thiopental 3-5mg/kg, lidocaine 1mg/kg, and a laryngeal mask airway (LMA) will be inserted. All patients will receive intravenous dexamathasone 0.1 mg/kg after induction and then will be studied in two groups. Anesthesia will be maintained with isoflurane 1-1.5% and O2/air (FiO2=50%) and half saline solution with a rate of 10cc/kg/hr will be infused. At the end of the surgery intravenous infusion of paracetamol 15mg/kg (1.5ml/kg of 1 gram paracetamol in 100 cc normal saline) or nomal saline with the same volume (1.5cc/kg) will be performed in 20 minutes in intervention or control group respectively . Two or more vomiting episodes will be treated with ondansetrone 0. 1mg/kg. The Facial Pain Scale will be used to measure postoperative pain after surgery and if the pain score to be measured is 3 or more, the patient will receive acetaminophen with a dose of 10mg/kg. Nausea and vomiting and pain score will be assessed in post-anesthesia care unit and in ward in 6-12 and 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310218768N2**
Registration date: **2014-05-20, 1393/02/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-05-20, 1393/02/30

Registrant information

Name

Mahshid Nikooseresht

Name of organization / entity

Hamadan university of Medical Sciences, Faculty of Medicine

Country

Iran (Islamic Republic of)

Phone

+98 81 3823 5383

Email address

nikooseresht@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

vice chancellor for research of Tehran university of medical science

Expected recruitment start date

2013-12-01, 1392/09/10

Expected recruitment end date

2014-07-01, 1393/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of intravenous paracetamol on post operative pain and nausea and vomiting in pediatric patients undergoing strabismus surgery

Public title

The effect of paracetamol on post operative pain, nausea and vomiting after strabismus surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children aged between 2 and 14 years, ASA physical status I and II scheduled for strabismus surgery under general anaesthesia Exclusion criteria: Those with hepatic or renal failure, known allergy to study drugs, those with a history of previous PONV or motion sickness, using antihistamine or antiemetic drugs or steroids in previous 24 hours before surgery,

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Tehran University of Medical Sciences

Street address

Sixth Floor, Central Organization of Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd., Tehran, Iran

City

Tehran

Postal code

Approval date

2013-01-15, 1391/10/26

Ethics committee reference number

210.22396.91.د

Health conditions studied

1

Description of health condition studied

acute postoperative pain

ICD-10 code

R52.0A

ICD-10 code description

Acute pain

2

Description of health condition studied

nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Nausea and vomiting

Timepoint

In recovery, 6 hours after surgery, 12 hours after surgery, 24 hours after surgery

Method of measurement

Questionare

2

Description

Pain score

Timepoint

In recovery, 6 hours after surgery, 12 hours after surgery, 24 hours after surgery

Method of measurement

Facial pain scale

Secondary outcomes

1

Description

Rescue analgesic dose

Timepoint

After 24 hours

Method of measurement

Questionare

2

Description

Rescue ondansetrone dose

Timepoint

24 hours after surgery

Method of measurement

Questionare

Intervention groups

1

Description

control group: Intravenous infusion of normal saline(1.5ml/kg) in 20 minutes at the end of surgery. Two or more vomiting episodes will be treated with ondansetrone 0. 1mg/kg. The Facial Pain Scale will be used to measure postoperative pain after surgery and if the pain score to be measured is 3 or more, the patient will receive acetaminophen with a dose of 10mg/kg. Nausea and vomiting and pain score will be assessed in post-anesthesia care unit and in ward in 6-12 and 24 hours after surgery.

Category

Treatment - Drugs

2

Description

Intervention group: Intravenous infusion of paracetamol 15mg/kg (1.5ml/kg of 1 gram paracetamol in 100 cc normal saline) in 20 minutes at the end of surgery. Two or more vomiting episodes will be treated with ondansetrone 0. 1mg/kg. The Facial Pain Scale will be used to measure postoperative pain after surgery and if the pain score to be measured is 3 or more, the patient will receive acetaminophen with a dose of 10mg/kg. Nausea and vomiting and pain score will be assessed in post-anesthesia care unit and in ward in 6-12 and 24 hours after surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi hospital

Full name of responsible person

Hamid Zahedi

Street address

Anesthesiolgy Department, Farabi hospital, Qazvin Square, South Kargar Ave, Tehran, Iran

City

Teharn

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research of Tehran university of medical science

Full name of responsible person

Dr. Yunesiyan

Street address

Sixth floor, central bulding of Tehran university of medical science, Ghods Aven, Keshavarz Blvd., Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

vice chancellor for research of Tehran university of medical science

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

Hamadan University of Medical Sciences

Full name of responsible person

Mahshid Nkooseresht M.D

Position

Assistant Professor of Anesthsiology, Fellowship of Pain managenent

Other areas of specialty/work

Street address

Anesthesiolgy Department, Besat hospital, ,Shahid Motahari Blvd, Resalat Square, Hamadan

City

Hamadan

Postal code

Phone

+98 81 1264 0049

Fax

Email

nikooseresht@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Mahshid Nikooseresht M.D

Position
Assistant Professor of Anesthesiology, Fellowship of Pain management
Other areas of specialty/work
Street address
Anesthesiolgy Department, Besat Hospital, Shahid Motahari Blvd, Resalat Square, Hamadan
City
Hamadan
Postal code
Phone
+98 81 1264 0049
Fax
Email
nikooseresht@umsha.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Hamadan University of Medical Sciences
Full name of responsible person
Mahshid Nikooseresht M.D
Position
Assistant Professor of Anesthesiology, Fellowship of Pain management
Other areas of specialty/work
Street address
Anesthesiolgy Department, Besat Hospital, Shahid Motahari Blvd, Resalat Square, Hamadan
City
Hamadan
Postal code
6514845471
Phone
+98 81 1264 0049
Fax
Email
nikooseresht@umsha.ac.ir
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