Prophylactic treatment for postoperative nausea and vomiting in children undergoing ambulatory surgery

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23862

Source
NTR

Brief title
Prophylaxis in PONV in children

Health condition

Postoperative nausea and vomiting, PONV, children, ambulatory surgery
Postoperatieve misselijkheid en braken, kinderen, pediatrische patiënten

Sponsors and support

Primary sponsor: Salud Sura, Medellin, Colombia. Rijksuniversiteit Groningen, the Netherlands.

Salud Sura, centro de cirurgia ambulatoria
Carrera 48 # 26-5
Medellin, Antioquia, Colombia
00575144480
Source(s) of monetary or material Support: Salud Sura, Medellin, Colombia.

Intervention

Outcome measures

Primary outcome

- Nausea

- Vomiting

Secondary outcome

- Pain

- Agitation

Study description

Background summary

Postoperative nausea and vomiting (PONV) continues to be a serious complication in children after surgery and the PONV-rate can be as high as 70% in high-risk patients without prophylaxis. The aim of this interventional study is a head-to-head comparison of various anti-emetic drugs that may help to develop a systematic review of pharmacological alternatives for PONV in children. The patients will be stratified based on the amount of risk factors and they will be randomly assigned to a treatment with dexamethasone alone, dexamethasone + a bolus of proposal or dexamethassone + ondansetron. Our primary outcomes are nausea and vomiting. Our secondary outcomes are pain and agitation. Rebleeding and other complications will be carefully monitored.

Study objective

- The incidence of PONV will be higher in the group receiving dexamethasone alone

- There will be no significant difference in the incidence of PONV between the two groups receiving two anti-emetic drugs

- There will be less postoperative agitation in the group receiving propofol

Study design

- 30 minutes after the surgery

- 2 hours after the surgery

- 24 hours after the surgery

Intervention

The patients will be stratified into three groups based on the amount of risk factors for PONV. Then they will be randomly assigned to one of the three treatments:

1. Dexamethasone + placebo

2. Dexamethasone + a bolus of propofol

3. Dexamethasone + ondansetron

Contacts

Public
Student Rijksuniversiteit Groningen
Vera-Maria Pavao Spanjer
Groningen
The Netherlands
Scientific
Student Rijksuniversiteit Groningen
Vera-Maria Pavao Spanjer
Groningen
The Netherlands

Eligibility criteria

Inclusion criteria

- Patients aged between 6 months and 12 years

- Patients undergoing ear-nose-throat surgery

- Patients undergoing general anesthesia longer than 30 minutes

Exclusion criteria

- Patients who already attained mernache

- Patients who had used antiemetic's within 24 hours preceding the surgery

- Patients who had used steroids during the previous 3 months preceding the surgery

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-04-2014
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-04-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4577
NTR-old	NTR4745
Other	Salud SURA, centro de cirurgia ambulatoria : SURA_25_04_2014

Study results