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

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- 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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23862

Bron
Nationaal Trial Register

Verkorte titel
Prophylaxis in PONV in children

Aandoening

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

Ondersteuning

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

Salud Sura, centro de cirurgia ambulatoria
Carrera 48 # 26-5
Medellin, Antioquia, Colombia
00575144480
Overige ondersteuning: Salud Sura, Medellin, Colombia.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Nausea
- Vomiting

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

- 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

Onderzoeksopzet

- 30 minutes after the surgery

- 2 hours after the surgery

- 24 hours after the surgery

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients aged between 6 months and 12 years

- Patients undergoing ear-nose-throat surgery

- Patients undergoing general anesthesia longer than 30 minutes

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	25-04-2014
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-04-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten