

# 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...

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON23862

### Bron

NTR

### Verkorte titel

Prophylaxis in PONV in children

### Aandoening

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

## Ondersteuning

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

Salud Sura, centro de cirugía ambulatoria  
Carrera 48 # 26-5  
Medellin, Antioquia, Colombia  
00575144480

**Overige ondersteuning:** Salud Sura, Medellin, Colombia.

# Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

- Nausea<br>
- 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 propofol or dexamethasone + 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

Student Rijksuniversiteit Groningen  
Vera-Maria Pavao Spanjer  
Groningen  
The Netherlands

### Wetenschappelijk

Student Rijksuniversiteit Groningen  
Vera-Maria Pavao Spanjer  
Groningen  
The Netherlands

## 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
Blinding:	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
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NTR-new	NL4577
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NTR-old	NTR4745
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Ander register Salud SURA, centro de cirugia ambulatoria : SURA\_25\_04\_2014

## Resultaten