The effect of ondansetron on persisting vomitin in children with gastro-enteritis presenting at primary care out of hours service.

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Oral ondansetron reduces the proportion of children that continue to vomit within the first 4 hours after presentation at the OHS when added to oral rehydration therapy compared to oral rehydration therapy alone.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26937

Bron
NTR

Verkorte titel
KOOKING

Aandoening

Huisartsgeneeskunde (General Practice), Kinderen (Children), Gastro-enteritis (gastroenteritis), Kosteneffectiviteit (cost-effectiveness), Misselijkheid (vomiting)

Ondersteuning

Primaire sponsor: Universitair Medisch Centrum Groningen
Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The proportion of children that continue to vomit within the first 4 hours after presentation at the OHS with acute gastro-enteritis.

Toelichting onderzoek

Achtergrond van het onderzoek

OBJECTIVE: To evaluate cost-effectiveness of ondansetron in children with acute gastro-enteritis (AGE) and vomiting at a general practitioner cooperative out-of-hours service (OHS)

RESEARCH QUESTION: What is the cost-effectiveness of ondansetron and oral rehydration therapy (ORT) compared to ORT alone?

HYPOTHESIS: With an effective one-intake-treatment that stops vomiting and consequently facilitates ORT, persisting vomiting and referral rate will be reduced and consequently will reduce costs

STUDY DESIGN: Pragmatic Randomized Controlled Trial

STUDY POPULATION: Vomiting children aged 6 months to 6 years with AGE attending OHS

INTERVENTION: Oral ondansetron added to ORT

SAMPLE SIZE We have to include 220 children in order to observe a significant reduction in persisting vomiting from an expected 35% to 15%

Doel van het onderzoek

Oral ondansetron reduces the proportion of children that continue to vomit within the first 4 hours after presentation at the OHS when added to oral rehydration therapy compared to oral rehydration therapy alone.

Onderzoeksopzet

Baseline (=T0), every hour after baseline for the first four hours (=T1 - T4) for the first day. Second day until the seventh (=T5-T11)

Onderzoeksproduct en/of interventie

Weight-based dose of oral ondansetron added to oral rehydration therapy.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Aged 6 months to 6 years;

2. At least four reported episodes of vomiting or diarrhoea during the last twenty-four hours preceding presentation

3. At least one reported episode of vomiting within the four hours preceding presentation;

4. Diagnosed with AGE by a general practitioner at the OHS.

5. Parental written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Use of anti-emetics in the previous 6 hours;

2. Known renal failure or hypoalbuminemia (as this could affect the assessment of hydration status);

3. Known diabetes mellitus or inflammatory bowel disease (as this could increase the risk of a complicated course);

4. A history of abdominal surgery, with suspected recurrence of original abdominal symptoms or strangulation ileus explaining current symptoms, according to the general practitioner.

5. Known sensitivity to 5-HT3 receptor antagonists;

6. Known prolonged QT interval;

7. Current use of QT prolonging medication;

8. Previous enrolment in the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2016
Aantal proefpersonen:	220
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43048
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5830
NTR-old	NTR5986
CCMO	NL59128.042.16
OMON	NL-OMON43048

Resultaten