The effect of ondansetron on referral rate in children with gastro-enteritis and vomiting.

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Oral ondansetron reduces the proportion of referred children to a (paediatric) emergency department when added to oral rehydration therapy compared to oral rehydration therapy alone.

Ethische beoordeling	Niet van toepassing
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21316

Bron
Nationaal Trial Register

Verkorte titel
KOOKING

Aandoening

General practice, Paediatrics, Acute gastroenteritis, Child, Cost-effectiveness, Antiemetic

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The proportion of referrals to a (paediatric) emergency department over a period of 5 days.

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, 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

PRIMARY CLINICAL OUTCOME IN COST EFFECTIVENESS ANALYSIS: the number of referrals to a paediatric emergency department prevented

SAMPLE SIZE We have to include 824 children in order to observe a significant reduction in referral rate from an expected 9% to 4.5%

ANTICIPATED HEALTHCARE EFFICIENCY GAIN: This intervention may prevent over 2000 hospital
admissions annually in the Netherlands

Doel van het onderzoek

Oral ondansetron reduces the proportion of referred children to a (paediatric) emergency department 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

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Aged 6 months to 6 years;

2. At least 24 hours with episodes of nonbilious, nonbloody vomiting;

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

4. At least one episode of diarrhea during the period of illness;

5. Parental written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Requiring direct referral to an emergency department according to GP;

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

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

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

5. A history of abdominal surgery;

6. Known sensitivity to 5-HT3 receptor antagonists;

7. Known prolonged QT-interval;

8. Current use of QT-prolonging medication;

9. 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 tijdelijk gestopt
(Verwachte) startdatum:	19-10-2015
Aantal proefpersonen:	1064
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41825
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4700
NTR-old	NTR4906
CCMO	NL50760.042.15
OMON	NL-OMON41825

Resultaten