

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

No registrations found.

Ethical review	Not applicable
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21316

Source

NTR

Brief title

KOOKING

Health condition

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

Sponsors and support

Primary sponsor: University Medical Center Groningen

Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Cessation of vomiting, the number of vomiting episodes during ORT, intravenous rehydration, hospital admission rate and duration, healthcare use and costs. A vomiting episode will be recorded by the parent when a forceful expulsion of stomach contents occurs. Episodes separated by no more than two minutes will be counted as a single episode. Nonproductive retching, spilling of oral contents, and drooling are not considered vomiting. Cessation of vomiting will be noted at the time of a vomiting episode after which no more than 1 vomiting episode is noted during a period of at least 1 day.

Study description

Background summary

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

Study objective

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.

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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 increase 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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Suspended
Start date (anticipated):	19-10-2015
Enrollment:	1064

Type:

Anticipated

Ethics review

Not applicable

Application type:

Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 41825

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

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

Study results