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

No registrations found.

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

Summary

ID

NL-OMON26937

Source
NTR

Brief title
KOOKING

Health condition

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

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Cessation of vomiting, the number of vomiting episodes during ORT, referral to a (pediatric) emergency department), 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, 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%

Study objective

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.

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

Public
Universitair Medisch Centrum Groningen

M.Y. Berger
Postbus 196

Groningen 9700 AD
The Netherlands
Scientific
Universitair Medisch Centrum Groningen

M.Y. Berger
Postbus 196

Groningen 9700 AD
The Netherlands

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

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:	Pending
Start date (anticipated):	01-11-2016
Enrollment:	220

Type: Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 43048
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results