The effect of oral ondansetron on referral rate in children aged 6 months to 6 years attending in primary care out of hours service with acute gastro-enteritis and vomiting.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal disorders
Study type	Interventional

Summary

ID

NL-OMON41825

Source
ToetsingOnline

Brief title
COOKING

Condition

- Gastrointestinal disorders
- Viral infectious disorders

Synonym
gastroenteritis, Stomach flu

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMw

Intervention

Keyword: Anti emetic, Children, Gastroenteritis, Primary care

Outcome measures

Primary outcome

The main study parameter is the number of referrals to a (pediatric) emergency department over a period of 7 days.

Secondary outcome

Secundary study parameters are: cessation of vomiting, the number of vomiting and diarrhea episodes during ORT, intravenous rehydration, hospitalization, quality of life, 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

Acute gastroenteritis (AGE) is a common childhood infectious disease, affecting almost all children younger than 5 years at least once. AGE is usually uncomplicated and self-limiting, however, it can lead to severe dehydration.

The risk for dehydration is highest if in addition to diarrhea also vomiting is present, which is a distressing symptom for both children and their caregivers. AGE is a very common reason for children to consult a general practitioner. Approximately 5% of consultations of children under five years old concern AGE. This percentage is similar for consultations during regular general practice hours and *evening, night and weekend* hours, delivered at general practitioners cooperative out-of hours services (OHS). Management of AGE depends on the severity of symptoms and the risk for dehydration. Recently, ondansetron, an antiemetic prescribed for vomiting caused by chemotherapy, was found to be effective in reducing hospital admissions in children with AGE. In the United States the use of ondansetron at paediatric emergency departments increased dramatically since then. Serious adverse events of orally administered ondansetron are not reported thus far. Herewith, oral ondansetron for young children with AGE and vomiting might be a potentially effective and a safe strategy to reduces referral rates and costs in primary care. It's cost-effectiveness in this setting, however, has never been demonstrated.

Study objective

The primary objective is to study the effect of oral Ondansetron and oral rehydration therapy on the number of referrals to a pediatric emergency department in children aged 6 months to 6 years attending an out-of-hours primary care service (OHS) with gastroenteritis in comparison to oral rehydration therapy alone.

Study design

A pragmatic randomised controlled trial with a total follow-up of 7 days after randomisation. There are two treatment groups. Group A receives ORT alone and group B will receive ORT and oral ondansetron.

Intervention

The intervention group receives oral ondansetron and ORT (both based on weight).

Study burden and risks

All participants will be assessed by a general practitioner and receive ORT (standard care). A parent kept diary with baseline measures, the EQ-D-Y questionnaire and health-related questions is completed daily. This diary will be collected at home by a research assistant. In a random selection of enrolled children body weight will be measured on a daily basis. The intervention group receives standard care and a single dose oral Ondansetron administered by the research assistant. Serious adverse events of orally administered Ondansetron are not reported thus far. Herewith, it reduced vomiting in children and

therefore might be an effective and safe strategy to improve well-being and reduce referral rates and costs in primary care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

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 as deemed by the GP
2/ Use of anti-emetics in the previous 6 hours; 3/underlying disease that could affect the assessment of hydration (such as renal failure or hypoalbuminemia);
4/ chronic disease increasing risk of a complicated course (such as diabetes or IBD.);
5/ history of abdominal surgery;
6/ known sensitivity to 5-HT3 receptor antagonists;
7/ known prolonged QT-interval or cardiac dysrhythmia;
8/ QT prolonging medication;
9/ previous enrollment in the study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-12-2015
Enrollment:	1064
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ondansetron
Generic name:	Ondansetron
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	16-02-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-09-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-11-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	07-12-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21316
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2014-004621-40-NL
CCMO	NL50760.042.15
OMON	NL-OMON21316