The added effect of oral ondansetron to care-as-usual on persisting vomiting in children aged 6 months to 6 years, presenting at primary care out of hours service with acute gastro-enteritis and concomitant vomiting

Published: 26-09-2016
Last updated: 19-03-2025

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

Summary

ID

NL-OMON43048

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 endpoint constitutes the proportion of children that continue to vomit within the first 4 hours after presentation at the OHS.

Secondary outcome

1. What are the costs of ondansetron and CAU compared to CAU in children presenting at OHS who are diagnosed by a GP as AGE?

2. What is the cost-effectiveness of ondansetron and CAU compared to just CAU?

3. What is the added effect of ondansetron to CAU on the proportion of children referred to a (pediatric) emergency department in children presenting at OHS with acute gastro-enteritis?

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 ondanetron for young children with AGE and vomiting might be a potentially effective and a safe strategy to stop vomiting and facilitate the use of ORT thereby reducing referral rates and costs in primary care OHS.

Study objective

The primary objective is to determine the added effect of oral ondansetron to care-as-usual (including ORT) (CAU) on persisting vomiting within the first 4 hours after presentation at an out-of-hours primary care service (OHS) in children aged 6 months to 6 years with acute gastroenteritis.

Study design

pragmatic randomized controlled trial with a total follow-up of 7 days after randomization. There are two treatment groups. Group A will receive care as usual and group B will receive ondansetron in addition to care as usual.

Intervention

Single weight-based dose of oral ondansetron.

Study burden and risks

All participants will be assessed by a general practitioner and receive care as usual (including ORT). A parent kept diary with baseline measures 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 care as usual and a single dose of oral ondansetron administered by the research assistant. Serious adverse events of orally administered ondansetron are not reported thus far. Therefore it might be an effective and safe strategy to stop vomiting and to facilitate ORT, thereby reducing 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 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:	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:	220
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:	26-09-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-01-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	08-05-2019
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: 26937
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2016-003582-25-NL
CCMO	NL59128.042.16
OMON	NL-OMON26937