Effect of domperidone and omeprazole in gastro-oesophageal reflux disease in infants between 0 and 2 years.

Published: 28-06-2007
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To measure the effect of domperidone and omeprazole on reflux-time, duration, and symptoms of GERD

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON37309

Source
ToetsingOnline

Brief title
Treatment with domperidone and omeprazole in GERD

Condition

- Gastrointestinal signs and symptoms

Synonym
GERD (=gastro-esophageal reflux disease), reflux

Research involving
Human

Sponsors and support

Primary sponsor: Flevoziekenhuis
Source(s) of monetary or material Support: De ziektekostenverzekeraar van de kinderen;die worden gezien door de kinderartsen;het betreft een reguliere diagnostiek en behandeling van kinderen met gastroesofageale reflux.

Intervention

Keyword: domperidone, Gastro oesophageal reflux disease, infants, omeprazole

Outcome measures

Primary outcome

Change in reflux time, reflux duration and symptoms before and after treatment

as measured by 24-h oesophageal pH monitoring, questionnairies, patient

controle

Secondary outcome

Physical examination, growth, laboratory results.

Study description

Background summary

Gastro-oesophageal reflux disease (GERD) is a common disease in infants between 0-2 years of age. GERD is diagnosed by a (golden standard). In case of GERD these infants are treated with dompridone and omeprazole. Is is unclear however if and to which degree these medicines and/or the combination of these medicines have effect on the oesophageal refluxtime and duration (as measured bij 24-h oesophageal pH monitoring). And what the effect is on the symptoms in infants between 0-2 years of age with GERD. With this study we want to measure the effect of medication on the symptoms of GERD in infants. Our hypothesis is that the combination of omeprazole and domperidone has a positive effect on the symptoms of GERD in infants between 0-2 years of age.

Study objective

To measure the effect of domperidone and omeprazole on reflux-time, duration, and symptoms of GERD

Study design

Open randomised controlled trial

Intervention

One group uses 1 mg/kg domperidone suspension (4dd), one group uses 2-3 mg/kg omeprazole mups (2dd) and one group with both domperidone and omeprazole.

Study burden and risks

Except for one extra 24-h oesophageal pH monitoring, this study results in no extra burden to the patients. The burden of a 24-h oesophageal pH monitoring is minimal, and there are no risks. We foresee no risks of the medicines that are used in this study, because these are registered medicines that are used within the indication range.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Gastro-oesophageal reflux disease diagnosed by 24-h oesophageal pH monitoring

Exclusion criteria

1. Gastro-oesophageal reflux disease for which treatment has started. 2. Infants with gastro-oesophageal reflux disease presenting with an apparant life threatening event (ALTE)

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):	18-01-2008
Enrollment:	90
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	losec-mups
Generic name:	omeprazole
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	motilium
Generic name:	domperidon
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	28-06-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-10-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-07-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-08-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-05-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-003067-46-NL
CCMO	NL16923.067.07