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

Published: 28-06-2007 Last updated: 11-05-2024

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

Ethical reviewApproved WMOStatusRecruitment stoppedHealth condition typeGastrointestinal signs and symptomsStudy typeInterventional

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.

1 - Effect of domperidone and omeprazole in gastro-oesophageal reflux disease in inf \ldots 13-05-2025

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

2 - Effect of domperidone and omeprazole in gastro-oesophageal reflux disease in inf ... 13-05-2025

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

Public Flevoziekenhuis

Hospitaalweg 1 1315 RA Almere NL **Scientific** Flevoziekenhuis

Hospitaalweg 1 1315 RA Almere NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Children (2-11 years)

Inclusion criteria

3 - Effect of domperidone and omeprazole in gastro-oesophageal reflux disease in inf ... 13-05-2025

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 gastrooesophageal 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
Туре:	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

4 - Effect of domperidone and omeprazole in gastro-oesophageal reflux disease in inf ... 13-05-2025

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
ССМО	NL16923.067.07