# 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 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.

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#### 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

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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 NI

#### Scientific

Flevoziekenhuis

Hospitaalweg 1 1315 RA Almere NL

## **Trial sites**

#### **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

#### Age

Children (2-11 years)

#### Inclusion criteria

#### **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