Effect of Prucalopride on esophagus in healthy volunteers.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24265

Source
Nationaal Trial Register

Health condition

Gastroesophageal reflux disease (GERD)
Functional dyspepsia
Delayed Gastric emptying
Heartburn
Gastro oesophagale reflux zikete (GORZ)
Functionele dyspepsie
Vertraagde maagontlediging
Zuurbranden

Sponsors and support

Primary sponsor: AMC afd. MDL/Motiliteit
Source(s) of monetary or material Support: Unrestrited grand van Shire/Movetis

Intervention

Outcome measures

Primary outcome

Number of esophageal reflux episodes during the 24-hr study.

Secondary outcome

1. Gastric emptying rate;

2. Esophageal contraction amplitudes;

3. LES resting pressure;

4. Esophageal acid exposure time;

5. Number of TLESRs.

Study description

Background summary

Double blind placebo controlled, randomized cross-over study. The study population will consist of 20 healthy male volunteers who will be measured in the AMC in Amsterdam. Aim of the study is to asses the effect of Prucalopride on esophageal contraction characterisitcs and lower esophageal sphincter pressure, gastric emptying and esophageal reflux parameters.

Study objective

Prucalopride accelerates gastric emptying and increases esophageal contraction amplitude and LES pressure and subsequently reduces gastroesophageal reflux.

Study design

Measurements will be performed after 5 days of either Prucalopride or placebo treatment and medication will be ingested each morning. In between the two treatments a wash out period of at least 7 days will be followed. On the first day subjects will arrive at the clinic in the morning after an overnight fast for the manometry test and impedance -pH test. the pH/impedance catheter will remain in situ to perform a 24 hour ambulatory measurement. On the second day the patient will arrive at the clinic in the morning and the pH/impedance catheter will be removed followed by a scintigraphy after a labeled meal.

Intervention

1. High resolution manometry (esophageal function study);

2. Impedance-pH recording (reflux study);

3. Standardized meal during the manometry and impedance;

4. Study medication/placebo: 4 mg a day during 6 days

5. Questionnaires;

6. Scintygraphy.

Contacts

Public
Meibergdreef 9
A.J. Bredenoord
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5661745
Scientific
Meibergdreef 9
A.J. Bredenoord
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5661745

Eligibility criteria

Inclusion criteria

1. Written informed consent;

2. Minimum age 18 years;

3. Male gender.

Exclusion criteria

1. Surgery of the GI tract other than appendectomy or cholecystectomy;

2. Motility disorders of the GI tract leading to delayed gastric emptying or altered intestinal motility;

3. A history of GI complaints;

4. Use of any medication with a potential effect on GI Motility that can not be stopped for the duration of the study with examination with radiation in the last year.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2011
Enrollment:	20
Type:	Actual

Ethics review

Positive opinion

Date:	18-04-2011
Application type:	First submission

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
NTR-new	NL2718
NTR-old	NTR2857
Other	EudraCT : 2011-001870-25
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A