Effect of Prucalopride on Gastroesophageal Reflux, Esophageal Motility and Gastric Emptying in healthy volunteers

Published: 02-11-2011
Last updated: 29-04-2024

To asses the effect of Prucalopride on esophageal contraction characteristics and lower esophageal sphincter pressure, gastric emptying and esophageal reflux parameters in healthy male subjects

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON35936

Source
ToetsingOnline

Brief title
Effect of Prucalopride on esophagus in healthy volunteers

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Gastroesophageal reflux, heartburn

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Shire,Shire/Movetis

Intervention

Keyword: GERD, GI Motility disorders, Healthy volunteers, Prucalopride

Outcome measures

Primary outcome

Number of esophageal reflux episodes during the 24-hr study

Secondary outcome

Gastric emptying rate (t1/2 emptying time)

Esophageal contraction amplitudes (proximal, middle and distal esophagus)

LES resting pressure

Esophageal acid exposure time (%time pH < 4)

Number of TLESRs

Study description

Background summary

Treatment of GERD (gastroesophageal reflux disease) fails in a small proportion of patients. As GERD is one of the most prevalent chronic disorders in the Western world, this small proportion of therapy-resistent patients encompasses a substantial part of the patient population and is it important to develope new medication for this population.
The cause of GERD is multifactorial, and a lower low esophageal sphincter (LES) pressure, weak esophageal peristalsis and slow gastric emptying may all play a role.
Prucalopride is a 5-HT4 receptor agonist that stimulates intestinal motility. Prucalopride (Resolor) recently received marketing authorization for the symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief.
No studies have been performed on the effect of Prucalopride on the human esophageal muscles and its sphincters and no data is present on the effect of Prucalopride on reflux characteristics.
In theory, effects on gastric emptying, esophageal motiltity and reflux

characteristics could be expected with prucalopride as with treatment with other 5-HT4 receptor agonists, suggesting that Prucalopride may be helpful for the treatment of upper gastrointestinal motility disorders such as GERD and functional dyspepsia
Hypothesis: Prucalopride accelerates gastric emptying and increases esophageal contraction amplitudes and LES pressure and subsequently reduces gastroesohageal reflux.

Study objective

To asses the effect of Prucalopride on esophageal contraction characteristics and lower esophageal sphincter pressure, gastric emptying and esophageal reflux parameters in healthy male subjects

Study design

Double blind placebo controlled, randomized cross-over design

Intervention

6 days placebo and 6 days of 4mg prucalopride once daily.

Study burden and risks

The risks of this study are very minor. Placement of the catheters could be uncomfortable and participation takes time, but this will be compensated by 400 euros by completion of the study.
The radiation exposure of the labeled pancake is very small; it consists of less than the natural annual radiation what is allowed per year for the Duch population.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Written Informed Consent
Minimum age 18 years
Male gender

Exclusion criteria

Abnormal renal function
Surgery of the GI tract other than appendectomy or cholcystectomy
Motlity disorders of the GI tract leading to delayed gastric emptying or altered intestinal motility
A history of GI complaints
Use of any medication with a potential effect on GI motility that can not be stopped for the duation of the study
Participation in another study with exposure to radiation in the last year

Study design

Design

Study phase:	3
Study type:	Interventional

Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2012
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Resolor
Generic name:	Prucalopride
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	EUCTR2011-001870-25-NL
CCMO	NL36606.018.11