Prokinetics to alter the position of the gastric acid pocket in Gastro Esophageal Reflux Disease.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26838

Source
NTR

Brief title
N/A

Health condition

Gastro esophageal reflux disease GERD
heartburn, zuurbranden.

Sponsors and support

Primary sponsor: Prof Dr G.E.E. Boeckxstaens
Meibergdreef 9
1105 AZ Amsterdam
Guy.boeckxstaens@med.kuleuven.be
Source(s) of monetary or material Support: Prof Dr G.E.E. Boeckxstaens
Meibergdreef 9
1105 AZ Amsterdam
Guy.boeckxstaens@med.kuleuven.be

Intervention

Outcome measures

Primary outcome

The rate of acid reflux episodes.

Secondary outcome

1. The rate of acid versus non acid reflux events;

2. The position of the acid pocket, relative to the lower esophageal sphincter and crural diaphragm;

3. The rate of TLESRs;

4. Gastric emptying.

Study description

Background summary

Gastro-esophageal reflux is a common phenomenon in which gastric contents flow back into the esophageal lumen, which can cause symptoms and/ or esophageal damage. Most reflux episodes occur during transient relaxations of the lower esophageal sphincter (TLESR). The rate of TLESRs is however comparable in healthy subjects and patients with gastro-esophageal reflux disease (GERD). In contrast, several studies agree that the risk to have acidic reflux during a TLESR is twice as large in GERD patients compared to healthy subjects. Esophageal acid exposure is of great importance for development of symptoms and/or esophageal damage.

Recently our lab has shown that the main factor in this difference is the position of the postprandial acid pocket. The acid pocket is an unbuffered pool of acid floating on top of the meal in the proximal stomach, where it is the most important source of refluxate. By injection of 99mTc-pertechnetate we were able to visualize this pool of acid scintigraphically, as 99mTc-pertechnetate is also secreted by parietal cells in the stomach.

The most important finding of the study was that in patients with a large hiatal hernia, the acid pocket may be trapped in the hiatal sac above the diaphragm allowing acid reflux to occur during episodes of low LES pressure. This explains the increased risk to have acidic gastroesophageal reflux during a TLESR, when the LES relaxes after swallowing or when LES pressure is low in patients with a hiatal hernia.

The macrolide Azitromycin is a bacterostatic antibiotic, with gastroprokinetic properties. Erytromycin, a comparable macrolide alters proximal gastric volume and postprandial

relaxtion time. Administration of Azitromycine in patients after lung transplant has shown to lower the rate of reflux episodes. Interestingly, it mainly alters the rate of acidic reflux events, suggesting that it alters the position of the acid pocket, as macrolides have no influence on acid secretion or TLESRs. Therefore, our aim is to show that the administration of Azitromycin leads to an altered position of the acid pocket scintigraphically, and it thereby changes the rate of postprandial acid reflux episodes.

Study objective

Our hypothesis is that alteration of the position of the postprandial acid pocket leads to less acid reflux events. The gastrokinetic properties of azithromycin might enable this effect, as was shown in the study by Mertens et al. {mertens}This study might show that treatment with prokinetics is beneficial in patients with GERD.

Study design

2 test days, separated by a min of 2 weeks.

Intervention

Administration of azitromycin.

Contacts

Public
Academic Medical Center (AMC), Department of Gastroenterology, C2-328,
P.O. Box 22660
G.E.E. Boeckxstaens
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5667375
Scientific
Academic Medical Center (AMC), Department of Gastroenterology, C2-328,
P.O. Box 22660
G.E.E. Boeckxstaens
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5667375

Eligibility criteria

Inclusion criteria

GERD patients with a hiatal hernia:

1. 18-65 years;

2. Esophagitis and/or pH-metry with an acid exposure of > 4,5%;

3. Hiatal hernia as seen on endoscopy or barium swallow of > 3 cm.

GERD patients without a hiatal hernia:

1. 18-65 years;

2. Esophagitis and/or pH-metry with an acid exposure of > 4,5%;

3. No hiatal hernia or a hiatal hernia < 2 cm as seen on endoscopy or barium swallow.

Exclusion criteria

1. Surgery of the gastrointestinal tract other then appendectomy;

2. Use of medication that interfere with gastrointestinal motility;

3. Inability to stop the use of proton pump inhibitors twice for one week;

4. Participation in another study with exposure to radiation within 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:	Recruiting
Start date (anticipated):	09-01-2009
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-08-2009
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	NL1858
NTR-old	NTR1970
Other	METC Academisch medisch centrum : MEC 09/099
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A