De invloed van Gaviscon op de acid pocket en zure reflux.

No registrations found.

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

Summary

ID

NL-OMON25536

Source
NTR

Health condition

GERD
Gastro-esophageal reflux disease
GORZ
gastro-oesofageale reflux ziekte

Sponsors and support

Primary sponsor: Prof. dr. G.E. Boeckxstaens
Academic Medical Center
Source(s) of monetary or material Support: Prof. dr. G.E. Boeckxstaens
Academic Medical Center

Intervention

Outcome measures

Primary outcome

Primary outcome is the number of acid reflux episodes detected on pH-impedance measurements.

Secondary outcome

Secondary outcomes are postprandial esophageal acid exposure, the rate of acid versus non acid reflux events, the number of non acid reflux events and the position of the acid pocket, relative to the crural diaphragm.

Study description

Background summary

The gastric acid pocket is the most important source of refluxate. It is hypothesized that very commonly used alginate-antacid formulations form a floating raft on top of the acid pocket. This is however never visualized in vivo. To visualize the alginate raft formation and to assess the effect of this raft formation on reflux parameters, we aimed to perform a randomised controlled study in which we compared Gaviscon, a alginate-antacid formulation to Antagel, a commonly used antacid.
We will compare these two over the counter medications in one postprandial measurement using pH-impedance testing to detect reflux episodes.

Study objective

We hypothesize that after alginate intake a raft is formed in the proximal stomach proximal of the gastric acid pocket, and that this raft affects the gastric acid pocket regarding acidity, position and size leading to less acid reflux events.

Study design

Patients undergo 1 postprandial measurement.

Intervention

1. The use of proton pump inhibitors has to be stopped 5-7 days prior to the study day;

2. On the study day, 350MBq Tc-pertechnetate is injected intravenously;

3. Randomized single oral administration of either 10 mL Gaviscon (Indium-labelled) or 10 mL Antagel;

4. Esophageal high-resolution manometry/pH-manometry to detect reflux eipsodes during 2 postprandial hours;

5. Scintigraphy.

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

1. GERD confirmed by pH-impedance (ph<4 in > 4,5 % of time or positive symptom association), or in patients with reflux esophagitis;

2. Written informed consent;

3. 18-75 years.

Exclusion criteria

1. Surgery of the gastrointestinal tract other than appendectomy;

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

3. Participation in another study with exposure to radiation;

4. Participation in another study within the last year;

5. Long segment of Barrett’s epithelium.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2012
Enrollment:	16
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-09-2012
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	NL3451
NTR-old	NTR3602
Other	MEC / CCMO : 11/279 / Nl37764.018.11;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
Previous publications on this subject from our group:

Beaumont H, Bennink RJ, de Jong J et al. The position of the acid pocket as a major risk factor for acidic reflux in healthy subjects and patients with GORD. Gut 2010;59(4):441-51.

Rohof WO, Bennink RJ, Hirsch DP et al. Effect of azithromycin on acid reflux, hiatus hernia and proximal acid pocket in the postprandial period. Gut. 2012 Jan 20. [Epub ahead of print].