The effect of Gaviscon on acid reflux episodes and on the position of the gastric acid pocket: A Scintigraphic study

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

Summary

ID

NL-OMON35613

Source
ToetsingOnline

Brief title
Gaviscon and Acid pocket

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Gastroesophageal reflux disease, heartburn

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Acid pocket, Alginate, Gastro-esophageal reflux disease (GERD)

Outcome measures

Primary outcome

- Acid reflux episodes

Secondary outcome

- Postprandial esophageal acid exposure

- The rate of acid versus non acid reflux events

- Non acid reflux events

- The position of the acid pocket, relative to the crural diaphragm

Study description

Background summary

Gastro-esophageal reflux is a physiological phenomenon in which gastric contents flow back into the esophagus. When reflux causes symptoms and/ or esophageal damage, it is referred to as gastro esophageal reflux disease (GERD), which is a very common chronic condition.(1)
Most reflux episodes occur after a meal, when the stomach is filled with recently ingested food. Until recently, it was thought that gastric contents mix well after a meal. However, almost immediately after a meal highly acidic reflux episodes occur. Fletcher et al have shown that in the proximal stomach an unbuffered pool of acid floats on top of the ingested food, which explains the acidic reflux immediately after a meal while the majority of the gastric contents are not acidic.(2) This unbuffered pool of acid is referred to as the gastric acid pocket. Recently, our lab has shown that the position of the acid pocket relative to the crural diaphragm mainly determines the acidity of the refluxate.(3) In patients with GERD, the fluid of the gastric acid pocket is located above or at the level of the diaphragm, and is as such the most important source of the refluxate.
Apart from an explanation for acid reflux episodes in GERD, the acid pocket also represents a unique therapeutic target.(4) Specifically, alginates, based on the concept of forming a gel-like barrier on top of gastric content, may displace or eliminate the *acid pocket*. (5) Alginates are natural

polysaccharide polymers isolated from brown seaweed (Phacophycae). On contact with gastric acid, alginate precipitates into a low density viscous gel of near neutral pH in a matter of seconds in vitro or a few minutes in vivo. (6;7) With the pH change, the sodium bicarbonate contained in the alginate-antacid formulation releases carbon dioxide, which is then trapped in the alginate gel causing it to float to the top of the gastric contents like a *raft*. (6;7)
Hence, alginate-based formulations with sodium bicarbonate may effect direct and immediate neutralisation of the acid pocket. The duration of in vivo action likely varies, but the raft of the original alginate based formulation (Gaviscon), remains in the stomach for up to 4 h and is retained on top of the meal. (7)

Study objective

Earlier studies suggest that Gaviscon alters the position of the acid pocket, as the number of acid reflux episodes decreased but the number of nonacid reflux events almost doubled after drug intake. (8) However, until now the formation of the raft in relation to the acid pocket has never been visualized in vivo. Therefore, we aim to perform a study to visualize the alginate raft formation and to assess the effect of alginates-antacid formulations on reflux parameters and the position of the acid pocket.

Study design

A randomized controlled study, comparing Gaviscon liquid to antacid suspension.

Intervention

Oral administration of 10 mL Gaviscon

Study burden and risks

Risk of participation in the study is limited. Radiation exposure and the introduction of the manometry catheter are the main risks and burden of the study.

Radiation
During two study day 350 MBq 99mTc-pertechnetate is applied intravenously. 99mTc-pertechnetate has no known side effects other then the radiation. Additionally gaviscon is labelled with 1 MBq of 113m-Indium. The radiation dose is in the intermediate category. Patients who recently participated in a study with radiation are excluded from the trial.

Group relatedness and benefit.
The patients studied all have proven GERD. Patients do not benefit from

participation in the study.

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

- GERD confirmed by pH-impedance (ph<4 in >4,5 % of time or positive symptom association), or in patients with reflux esophagitis
- Written informed consent
- 18-75 years;

Exclusion criteria

- surgery of the gastrointestinal tract other then appendectomy
- inability to stop the use of proton pump inhibitors for one week;
- participation in another study with exposure to radiation within the last year;
- long segment of Barrett*s epithelium;

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):	01-01-2012
Enrollment:	32
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Antagel
Generic name:	aluminiumoxide and magnesiumhydroxide
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Gaviscon
Generic name:	Antacid-alginate formulation consisting of sodium alginate and potassium hydrogen carbonate
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	08-11-2011
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	EUCTR2011-003680-29-NL
CCMO	NL37764.018.11