# Analysis of the gastric acid pocket

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To obtain fluid from the the gastric acid pocket to:1.) Compare fluid of patients on ppi, patients with Barrett's esophagus and volunteers2.) to assess the properties of the fluid to develop a reliable in vitro model

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational invasive

# **Summary**

### ID

NL-OMON36206

**Source** ToetsingOnline

**Brief title** acid pocket in healthy volunteer

# Condition

• Gastrointestinal motility and defaecation conditions

**Synonym** gastroesophageal reflux disease (GERD), 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, gastro esophageal reflux disease (GERD)

#### **Outcome measures**

#### **Primary outcome**

Pepsin concentration and activity

#### Secondary outcome

Trypsin concentration and activity

pH, density, viscosity

# **Study description**

#### **Background summary**

Gastro-esophageal reflux is a common 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.

Most reflux episodes occur after a meal, when the stomach is filled. Until recently, it was thought that gastric contents mix well after a meal. However, already soon after a meal highly acidic reflux episodes occur. Fletcher et al have shown that an unbuffered pool of acid floats on top of the meal in the proximal stomach, which explains the acidic reflux after a meal, and this they have called the gastric acid pocket. Recently, our lab has shown that the position of the acid pocket in relation to the crural diaphragm mainly determines the acidity of the refluxate. In patients with GERD, the fluid of the gastric acid pocket is located above or at the level of the diaphragm, and is then the most important source of the refluxate. In a substudy, we have shown that it is possible to obtain the fluid of the acid pocket by applying suction via a gastric tube. Thereby, suction of the pocket enables us to analyze the composition of the refluxate, which is of importance in the generation of symptoms and/or mucosal damage.

Until now, the acidity and localisation of the pocket are the only factors that have been studied. Factors in refluxate that are known to cause either symptoms or mucosal damage, are pepsin, trypsin and bile acids. The composition of gastro-esophageal refluxate has been analyzed before. In this study, it was shown that acid and pepsin in refluxate were the most important predictors of mucosal damage. Nowadays, patients with GERD have potent acid suppressive therapy, which was unavailable at the time of this study. Acid suppressive therapy leads to less acid reflux, and probably to inactivity of pepsin. Currently, a study is conducted in which the acid pocket composition in patients with acid suppressant resistant symptoms is analyzed. (MEC 10/037) To compare data to patients with GERD, the data from this study in healthy volunteers will be used.

Furthermore, although frequently used therapies like antacids and alginates are thought to influence the gastric acid pocket, this has not yet been studied. Analysis of the fluid of the gastric acid pocket will be used to come to a reliable in vitro model of the acid pocket. Using an in vitro model, the influence of current therapies can be evaluated and potential new therapies can be tested.

#### **Study objective**

To obtain fluid from the the gastric acid pocket to:

1.) Compare fluid of patients on ppi, patients with Barrett's esophagus and volunteers

2.) to assess the properties of the fluid to develop a reliable in vitro model

#### Study design

This is a non-therapeutic study

#### Study burden and risks

the burden is limited to one study visit in which a scintigraphy and suction via an inserted gastric tube is performed. Risk is limited, but there is radiation exposure and the the introduction of the gastric tubes.

# 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**

Healthy volunteers: Written informed consent Age 18-65 years Patients with Barrett\*s esophagus: Written informed consent Age 18-65 years A circular Barrett segment confirmed by histopathology

# **Exclusion criteria**

GERD Surgery of the GI-tract other than appendectomy Gastro-intestinal complaints Medication influencing acid secretion or GI motility. Participation in another study with exposure to radiation within the last year patients: Participation in another study with exposure to radiation within the last year inability to stop with PPI for 1 week

# Study design

### Design

Study type:

Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-04-2011
Enrollment:	20
Туре:	Anticipated

# **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 CCMO **ID** NL35619.018.11