

# Stress and Oesophageal Acid Perception

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To investigate the relationship between acute psychological stress and perception of acid in the distal oesophagus in healthy volunteers and GORD patients.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gastrointestinal conditions NEC
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON32280

### Source

ToetsingOnline

### Brief title

Stress and Oesophageal Acid Perception

### Condition

- Gastrointestinal conditions NEC

### Synonym

gasto-oesophageal reflux disease, heartburn

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Ministerie van OC&W

### Intervention

**Keyword:** Acid Perception, Oesophagus, Stress

## Outcome measures

### Primary outcome

For both measurements time necessary to provoke first perception, discomfort and pain during the acid perfusion will be assessed.

### Secondary outcome

Systolic and diastolic blood pressure (mmHg) and heart rate (beats/min) will be assessed during both measurements in order to assess the reaction to mental stress task.

The State and Trait Anxiety Inventory (STAI)/Zelf Beoordelings Vragenlijst (ZBV) is scored before introducing the manometry and pH catheter on both measurement days.

The pH recording will show pH levels in the distal oesophagus during the acid perfusion test continuously. Afterwards, total time with  $\text{pH} < 4$  will be calculated and presented in minutes.

## Study description

### Background summary

Many patients with gastro-oesophageal reflux disease (GORD) report an association between stress and symptoms of GORD. Results of studies using experimentally induced stress show an increase in symptoms but no increase in objective reflux parameters. This points towards a role of hypersensitivity to gastro-oesophageal reflux during stressful circumstances. We hypothesize that the sensitivity of the distal oesophagus to acid might be modulated by acute stress.

### Study objective

To investigate the relationship between acute psychological stress and

perception of acid in the distal oesophagus in healthy volunteers and GORD patients.

## **Study design**

The study consists of two parts. First the study is conducted with healthy volunteers. After all measurements are completed, the same measurements are performed with GORD patients. All participants will undergo stationary manometry, pH monitoring and an acid perfusion test twice, one measurement without and one with the presence of an acute psychological stressor. The order of these two measurements will be randomized. Before each measurement participants will fill in a questionnaire in order to compare subjects' anxiety scores on the two different days. We will use a modified Raven Progressive Matrices IQ test to induce psychological stress.

## **Study burden and risks**

Participants will undergo routine stationary oesophageal manometry, pH monitoring and acid perfusion test twice. There will be one week between both measurements. Oesophageal manometry and pH monitoring are routine investigations at our department and involve no risks for the participants.

## **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: no symptoms/history of gastro-oesophageal reflux disease

Patients with gastro-oesophageal reflux disease: previously diagnosed with gastro-oesophageal reflux disease with good association between symptoms and reflux episodes

### Exclusion criteria

Surgery of the gastro-intestinal tract

Psychiatric disorders

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	05-02-2008
Enrollment:	25
Type:	Actual

## Ethics review

Approved WMO

Date: 18-12-2007

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

## 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
CCMO	NL20540.041.07