

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.

Ethical review	Not approved
Status	Will not start
Health condition type	Gastrointestinal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON31351

Source

ToetsingOnline

Brief title

Stress and Oesophageal Acid Perception

Condition

- Gastrointestinal conditions NEC

Synonym

gastro-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 test will be assessed.

Secondary outcome

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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 oesophageal 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 randomised. Before each measurement participants will have to 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 acute 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.

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

Exclusion criteria

Surgery of the gastro-intestinal tract

Study design

Design

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

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	25
Type:	Anticipated

Ethics review

Not approved	
Date:	21-08-2007
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	NL17244.041.07