# The role of obesity in nocturnal heartburn

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

# Summary

### ID

**NL-OMON32693** 

**Source** ToetsingOnline

Brief title Nocturnal heartburn and obesity

### Condition

• Gastrointestinal motility and defaecation conditions

#### Synonym nocturnal GERD, nocturnal 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: 24 h pH metry, High resolution manometry, Nocturnal reflux, Obesity

### **Outcome measures**

#### **Primary outcome**

The difference in nocturnal reflux pattern (reflux time / 24 h, frequency of

reflux episodes, LES pressure) between obese and normal-weight subjects with

GERD.

#### Secondary outcome

n.v.t.

# **Study description**

#### **Background summary**

More than half of patients with chronic gastroesophageal reflux (GERD) report nocturnal symptoms. Consequences of nocturnal reflux include poor sleep quality, daytime fatigue, difficulty initiating sleep or arousals from sleep, and impaired work productivity.

A dose-dependent relationship between obesity and reflux was described before. Several mechanisms -among others increased intragastric pressure, the presence of a hiatus hernia and more frequent TLESRs - play a role in this relation. In this study, the role of obesity in the pathophysiology of nocturnal acid reflux will be assessed. This has not been studied before. Our hypothesis is that obese subjects -as compared to lean GERD patients- will have more gastroesophageal reflux during the night. The above mentioned factors will contribute to this increase.

### **Study objective**

The first aim is to determine the amount of nocturnal reflux (reflux time / 24 h) in obese subjects compared to normal weight subjects. Secondary objectives are to identify possible mechanisms which cause nocturnal reflux in this patient group and to identify the relation between

anthropometric parameters (BMI and waist circumference) and the reflux pattern.

### Study design

In a prospective study, the nocturnal reflux pattern will be assessed; pHmonitoring and high resolution manometry will be carried out overnight. Esophageal impedance will also be measured to assess the role of non-acid and gaseous nocturnal reflux. Patients will be admitted to the hospital for one night, because the combination of these measurements can not be done ambulatory.

#### Study burden and risks

Patients will undergo nocturnal pH-metry and high resolution manometry. Therefore they will be admitted for one night in the UMC Utrecht. The combination of these probes is necessary to determine the role of LES integrity and esophageal peristalsis in the pathogenesis of obesity. The risk associated with these procedures is limited. In the literature several studies with combined ph-metry and manometry can be found. The probes are -generaly speaking- tolerated normal during sleep.

# Contacts

#### Public

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# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

- Man and woman > 18 years of age
- Proven nocturnal GERD (pH < 4 during > 3 % of supine position)
- Non-obese subjects: BMI 18.5-24.9 kg/m2
- Obese subjects: BMI > 30 kg/m2

# **Exclusion criteria**

- Pre-existent esophageal motility disorders
- Proven obstructive sleep apnea with CPAP therapy
- Inability to stop medication that affects the motility of the upper gastrointestinal tract (anticholinergic drugs, theophylline, calcium blocking agents, opioids)

# Study design

# Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Basic science	

### Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	20
Туре:	Anticipated

# **Ethics review**

Not approvedDate:17-11-2009Application type:First submissionReview 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** CCMO ID NL30255.041.09