

# Combined high-resolution manometry and impedance measurement as diagnostic tools in the rumination syndrome

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

## Summary

### ID

NL-OMON34476

### Source

ToetsingOnline

### Brief title

HRM, impedance and the rumination syndrome

### Condition

- Gastrointestinal motility and defaecation conditions

### Synonym

vomiting

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

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

## Intervention

**Keyword:** high resolution manometry, impedance, regurgitation, rumination syndrome

## Outcome measures

### Primary outcome

The occurrence of a specific gastroesophageal pressure-flow pattern immediately before or simultaneously with the regurgitation event

### Secondary outcome

Other esophageal and intragastric pressure tracings

Esophageal pH-metry tracings

Esophageal impedance tracings

## Study description

### Background summary

Rumination syndrome is a functional gastroduodenal disorder of unknown etiology characterized by persistent or recurrent regurgitation of recently ingested food into the mouth, typically not preceded by retching and occurring without nausea<sup>1-3</sup>.

Diagnosis is currently based on clinical features as defined by the Rome III criteria<sup>1,4</sup>. Differentiating rumination syndrome from other pathology that can present with similar complaints can be challenging. Gastro-esophageal reflux disease can present with regurgitation symptoms, regurgitation can occur secondary to gastroparesis, symptoms can be mistaken for aerophagia or excessive belching and other functional disorders can also be mistaken for rumination syndrome<sup>1</sup>. Rumination syndrome is currently a syndrome that can only be diagnosed by clinical observation by a physician with expertise in esophageal motility disorders. As there are only clinical criteria and no objective tests to diagnose rumination, this syndrome is an underappreciated condition in which patients are often misdiagnosed<sup>1</sup>. Patients often have symptoms for several years and have consulted many different physicians before rumination syndrome is diagnosed<sup>5</sup>.

A relatively new technique is impedance recording which measures not only acid reflux but also non-acid-reflux and gas-reflux. This offers the advantage of differentiation between belching and regurgitation by differentiating gaseous reflux from liquid reflux and also detect non-acidic regurgitation<sup>6</sup>. Two case reports described the role of combined manometry/impedance in patients with rumination syndrome. The authors observed an increase in intra-abdominal pressure followed by an increase in intra-esophageal pressure in all channels (common cavity) that was associated with esophageal reflux on impedance monitoring<sup>7,8</sup>. Recently, Rommel et al were able to successfully differentiate between belching-regurgitation and rumination syndrome using manometry/impedance measurement by differentiating gas reflux from fluid reflux with impedance measurement<sup>9</sup>.

A second relatively new technique is high resolution manometry which offers the advantage of a more detailed measurement of the whole esophageal body including measurement of the upper esophageal sphincter<sup>10</sup>.

Despite the fact that rumination syndrome shows typical patterns when measured by combined (high-resolution) manometry and impedance<sup>7,8</sup>, only limited efforts have yet been made to differentiate rumination syndrome from other pathology, using these objective measurements. Interpretation of esophageal function tests in patients suspected of rumination syndrome is therefore challenging due to absence of objective criteria and can only be performed by an expert physician. These shortcomings in current diagnostic tools for the rumination syndrome contribute to under-appreciation and often a misdiagnosis of the syndrome. Objective criteria are of clinical importance to allow correct and quick recognition of the syndrome even by physicians with limited expertise in esophageal motility disorders thereby contributing to early recognition and proper treatment.

## **Study objective**

The aim of this study is to measure and describe differences in manometric and impedance patterns in patients with an initial presentation of regurgitation and/or vomiting with and without clinical diagnosis of rumination syndrome. With these differences we will subsequently be able to create objective criteria in the future that can help to distinguish rumination syndrome from other, rather similar presenting disorders.

## **Study design**

A prospective study using combined high-resolution manometry and impedance measurements in which patients presenting with true rumination are compared to patients with regurgitation and vomiting that do not have the rumination syndrome.

## **Study burden and risks**

Patients have to stop PPI or medication influencing GI-motility and have to travel to the AMC. There are no known risks associated with these investigations.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

11 patients with rumination syndrome

11 patients with initial complaints of regurgitation or vomiting but without clinical diagnosis of rumination syndrome

## Exclusion criteria

Surgery of the GI tract other than appendectomy or cholecystectomy  
Inability to stop the use of medication influencing GI motility for one week  
Inability to stop the use of proton pump inhibitors for one week  
Abnormal endoscopic gastroesophageal findings other than esophagitis or hiatal hernia  
Abdominal ultrasound and/or abdominal x-ray suggestive of intestinal obstruction

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	29-04-2010
Enrollment:	22
Type:	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**

<b>Register</b>	<b>ID</b>
CCMO	NL32506.018.10