

# Effect of endoscopic treatments of Barrett's oesophagus on oesophageal motility and reflux

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To compare oesophageal motility as well as reflux characteristics before and after endoscopic treatment of the Barrett segment, and to study differences between patients treated with SRER or BÂRRx.

<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-OMON30256

### Source

ToetsingOnline

### Brief title

Motility and reflux after endoscopic treatment Barrett

### Condition

- Gastrointestinal conditions NEC

### Synonym

oesophageal motility, reflux

### Research involving

Human

### Sponsors and support

**Primary sponsor:** St. Antonius Ziekenhuis

**Source(s) of monetary or material Support:** Janssen-Cilag

## Intervention

**Keyword:** Barrett's oesophagus, Endoscopic treatment, gastroesophageal reflux, oesophageal motility

## Outcome measures

### Primary outcome

Using oesophageal manometry the following parameters will be assessed: % of contractions that are peristaltic, contraction amplitude and duration in the proximal and distal oesophagus, lower oesophageal sphincter pressure and relaxation nadir pressure. Impedance-pH measurements will be analyzed for number and type (acid, weakly acidic, liquid, gas or mixed liquid-gas reflux) of reflux episodes and proximal extent of the reflux episodes. In addition, % of time with oesophageal pH<4.0 will be determined.

### Secondary outcome

-

## Study description

### Background summary

Endoscopic surveillance is recommended for patients with Barrett's oesophagus because of its malignant potential and the hope to detect dysplasia before it progresses to adenocarcinoma. Oesophagectomy has traditionally been recommended for patients with high-grade dysplasia. Oesophagectomy is an operation with considerable mortality and morbidity. Recently, several less invasive endoscopic treatments have been developed. Two of these techniques are stepwise radical endoscopic resection (SRER) and BARRx. Little is known about oesophageal motility and reflux characteristics after endoscopic treatment with SRER and BARRx

### Study objective

To compare oesophageal motility as well as reflux characteristics before and

after endoscopic treatment of the Barrett segment, and to study differences between patients treated with SRER or BÂRRx.

## **Study design**

Patients will undergo routine oesophageal manometry and ambulatory 24-hr impedance-pH monitoring twice, one measurement before and one measurement after endoscopic treatment.

## **Study burden and risks**

Oesophageal manometry and the 24-hr reflux monitoring test after patients have stopped their medication are routine clinical practice at our department for patients with therapy-resistant reflux symptoms. Oesophageal manometry and impedance-pH reflux monitoring tests are CE registered and are widely used in daily practice.

For this study patients will undergo a second oesophageal manometry and 24-hr reflux monitoring after endoscopic treatment for their high-grade dysplasia. These second manometry and impedance-pH measurement are not indicated for routine clinical testing and are required to study the effect of the treatment on oesophageal motility and reflux. There is no direct advantage for the patients to participate.

## **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

Barrett's oesophagus with high-grade dysplasia

Scheduled for endoscopic treatment with SRER or BARRx

### Exclusion criteria

Prior surgery of the stomach or oesophagus

condition with contraindicates the cessation of PPI therapy such as peptic ulcer disease

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 26-02-2007

Enrollment: 20

Type: Actual

## Ethics review

Approved WMO

Date: 18-12-2006

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## 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	NL14589.100.06