

# Studying esophageal pressure characteristics using high-resolution manometry: A comparison between solid state catheters and water-perfused catheters

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

## Summary

### ID

NL-OMON39369

### Source

ToetsingOnline

### Brief title

A comparison between solid state catheters and water-perfused catheters

### Condition

- Gastrointestinal motility and defaecation conditions

### Synonym

manometry

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

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

## Intervention

**Keyword:** esophagus, Manometry

## Outcome measures

### Primary outcome

Resting pressure of the lower esophageal sphincter

### Secondary outcome

LES relaxation pressure

Distal contractile amplitude

## Study description

### Background summary

Since the introduction of esophageal manometry in the mid 1950s many different manometric systems have been introduced. The current gold-standard for measuring esophageal pressure characteristics is the so-called high-resolution manometry which refers to catheters with 1-cm manometric sensor spacing at the position of the esophagogastric junction. Two different catheters are currently available for clinical practice 1) catheters with water-perfused pressure sensors, the so-called water-perfused catheters and 2) catheters with solid-state pressure sensors, the so-called solid-state catheters. The current classification for esophageal motility disorders as well as normal values for high-resolution manometry have all been developed using solid-state catheters. Normal-values for water-perfused high-resolution catheters are not available and it is currently unknown whether pressure levels as measured by solid-state catheters are different from water-perfused catheters. sure levels as measured by solid-state catheters with water-perfused catheters.

### Study objective

Therefore, the aim of this study is to determine normal-values for esophageal pressure characteristics using a water-perfused high-resolution manometry

catheter. Furthermore, we aim to compare pres

### **Study design**

A comparative study using solid-state high-resolution manometry catheters and water-perfused high-resolution manometry catheters.

### **Study burden and risks**

none

## **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

Written informed consent  
Minimum age: 18 years

## Exclusion criteria

Gastrointestinal complaints

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL  
Recruitment status: Recruitment stopped

Start date (anticipated): 31-05-2013

Enrollment: 31

Type: Actual

## Ethics review

Approved WMO  
Date: 19-02-2013  
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	NL39310.018.11