Prediction of succesful oesophageal bolus transport with High-Resolution Manometry (HRM)

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The main objective of this study is to investigate whether HRM is able to predict bolus transport of solids and liquids in the oesophagus as adequately as the gold standard, i.e. videofluoroscopy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational invasive

Summary

ID

NL-OMON32598

Source
ToetsingOnline

Brief title
Prediction of oesophageal bolus transport with HRM

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
difficulty with swallowing, dysphagia

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: bolus transport, dysphagia, HRM, oesophagus

Outcome measures

Primary outcome

The main parameters studied are the intra-bolus pressure, peristaltic amplitude and sphincter pressure. Prior to the study, patients* symptoms will be assessed using questionnaires. Furthermore, after each swallow the subjects will have to indicate whether they believe whether or not complete bolus transport has occurred.

Secondary outcome

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Study description

Background summary

Since its introduction in the 1950s oesophageal manometry has been the mainstay in the evaluation of oesophageal motility disorders. With conventional manometry pressures are usually measured at 5 cm intervals in the oesophagus and its sphincters. High-Resolution manometry (HRM) is a relatively new tool in the evaluation of oesophageal motility and can be regarded as a technical improvement over conventional manometry. Compared to conventional manometry, the catheter itself contains more sensors and offers the possibility of studying peristalsis at 1-cm intervals in the entire oesophagus. In addition, pseudo 3D topographic plots or colour plots can be made, and this facilitates the interpretation of the results. In analysing patients with oesophageal motility disorders, is has been suggested that HRM improves understanding of the precise pathophysiologic mechanism. In particular, in patients with symptoms of dysphagia in which endoscopy and conventional manometry has provided no explanation, HRM might be useful as it can hopefully provide a better explanation for the symptoms, for example by revealing a localized motility defect causing stasis of the swallowed bolus.
Until now, the gold standard for measurement of bolus transit in the oesophagus has been videofluoroscopy. However, this technique exposes subjects to ionizing

radiation and is not widely available. It is therefore relevant to investigate whether HRM can also predict bolus transport in the oesophagus to the same extent as fluoroscopy does.

Study objective

The main objective of this study is to investigate whether HRM is able to predict bolus transport of solids and liquids in the oesophagus as adequately as the gold standard, i.e. videofluoroscopy.

Study design

observational study

Study burden and risks

Participants will simultaneously undergo stationary high-resolution manometry (HRM) and videofluoroscopy with barium swallows. In addition, they will be requested to fill in a questionnaire in which the symptoms of dysphagia are assessed. HRM and fluoroscopy are routine investigations at our department. No specific risk is associated with these investigations.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3508 GA Utrecht
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3508 GA Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

dysphagia, negative upper endoscopy, above 18 years, written informed consent

Exclusion criteria

surgery of the gastrointestinal tract, absence of informed consent, abnormalities on upper endoscopy

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):	15-08-2009
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	High-Resolution Manometry
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-01-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-09-2009
Application type:	Amendment
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	NL24288.041.08