Normal values of oesophageal High-Resolution Manometry

Published: 23-06-2009
Last updated: 06-05-2024

The main objective of this study is to obtain normal values for high-resolution manometry. The second objective is to investigate the inter- and intra-individual variability of the measured parameters.

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

Summary

ID

NL-OMON35159

Source
ToetsingOnline

Brief title
Normal values of oesophageal High-Resolution Manometry

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
-

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 that are important in routine clinical manometry:

propagating velocity, lower oesophageal sphincter (LES) pressure and LES nadir

pressure, the proximal and distal contraction propagation velocity and proximal

and distal oesophageal peristaltic amplitude.

Secondary outcome

Interindividual and intraindividual variability.

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.
However, the obtained large data sets, gathered with HRM, constitute also its limitation in widespread clinical implementation. Mainly, what is to be regarded *normal* in the new paradigm is of particular importance since without normal values clinical interpretation of measurements of patients is not

possible.
In addition, the inter- and intra-individual variability of the parameters used is not known.

Study objective

The main objective of this study is to obtain normal values for high-resolution manometry. The second objective is to investigate the inter- and intra-individual variability of the measured parameters.

Study design

observational study

Study burden and risks

Participants will undergo stationary oesophageal high-resolution manometry (HRM). HRM is a routine investigation at our department. No specific risk is associated with this investigation.

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

Written informed consent
Age above 18 years
No upper gastrointestinal symptoms

Exclusion criteria

Surgery of the gastrointestinal tract
Absence of informed consent
Gastrointestinal symptoms

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):	24-08-2009
Enrollment:	52
Type:	Actual

Ethics review

Approved WMO Date:	23-06-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-12-2010
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	NL25991.041.08