Reproducibility of provocative tests during esophageal high-resolution manometry

Published: 05-07-2023
Last updated: 21-09-2024

The main objective of this study is to examine the reproducibility of provocative tests and single wet swallows by high-resolution manometry in patients with dysphagia and/or reflux complaints

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

Summary

ID

NL-OMON53367

Source
ToetsingOnline

Brief title
REPRO

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
dysphagia, esophageal motility disorder

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: manometry, provocative, reproducibility, tests

Outcome measures

Primary outcome

The main study endpoint is the reproducibility of provocative tests during high-resolution manometry. The reproducibility is determined by concordance of normal and abnormal outcomes of each provocative test.

Secondary outcome

• Reproducibility of single wet swallows determined by concordance of normal and abnormal outcomes.

• Agreement of outcome variables between first and second measurement within one test determined by intraclass correlation coefficient (ICC)

• Change in diagnosis of esophageal motility disorder after second measurement

• Agreement of different outcome variables between single wet swallows and provocative tests.

Study description

Background summary

Dysphagia is the main complaint of patients with an esophageal motility disorder and this complaint can have a considerable impact on health and quality of life. The Chicago Classification, which is updated in 2021 to version 4.0, is a classification of esophageal motility disorders which can be used to make a diagnose after performing high-resolution manometry. Standard manometry shows the peristaltic contraction and the function of the lower esophageal sphincter after ten single wet swallows. According to the Chicago classification version 4.0, the standard single wet swallows are followed by provocative tests (e.g. multiple rapid swallows or solid test swallows). It is presumed that provocative tests can be helpful in clinical management and that

abnormal results of provocative tests in case of normal standard manometry can clarify patients* complaints. However, results of standard manometry are not fully compatible with results of provocative tests and it is not clear which results are the best reflection of the esophageal condition

Study objective

The main objective of this study is to examine the reproducibility of provocative tests and single wet swallows by high-resolution manometry in patients with dysphagia and/or reflux complaints

Study design

A single center, prospective, single-arm, non-blinded study.

Study burden and risks

The burden for the subjects is the completion of the dysphagia questionnaires and two visits for high-resolution manometry of which one visit is already scheduled because of clinical diagnostic work-up for the dysphagia complaints. The risks related to the high-resolution manometry are very limited as this measurement is routinely performed at the Gastroenterology and Hepatology Department of the Amsterdam UMC. After the measurement, subjects can experience irritations of the nose or throat because of the placement of the manometry catheter. This feeling will be temporary and will soon disappear. The findings of this study could be helpful to accurately diagnose esophageal motility disorders in future patients with complaints of dysphagia and could be helpful to choose the optimal treatment.

Contacts

Public
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Amsterdam UMC

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Complaints of dysphagia and/or reflux;
• Age of 18 years or older;
• High-resolution manometry as part of routine clinical practice;
• Written informed consent;

Exclusion criteria

• (Suspect) esophageal motility disorder for which treatment is scheduled between the two manometry measurements;
• Use of medication which affect gastrointestinal motility that cannot be stopped (e.g. prokinetics or opioids);
• Another explanation for their dysphagia complaint on previous upper endoscopy (within three years);
• Previous gastroesophageal surgery (e.g. bariatrics or fundoplication);
• Coeliac disease;
• Insufficient Dutch or English language skills to understand information about the measurement.

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-10-2023
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	05-07-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-03-2024
Application type:	Amendment
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

Register	ID
CCMO	NL83507.018.23