Ambulatory 24-h reflux monitoring: a comparison between glass-, antimony- and ISFET electrodes

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To compare oesophageal acid exposure time measured with glass, ISFET and antimony electrodes in patients with reflux symptoms and basic pH electrode characteristics, response time, sensitivity and drift between the 3 types of pH electrodes.

Ethical review	Not approved
Status	Will not start
Health condition type	Gastrointestinal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON32064

Source
ToetsingOnline

Brief title
pH electrodes reflux monitoring

Condition

- Gastrointestinal conditions NEC

Synonym
GORD, heartburn

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Janssen-Cilag

Intervention

Keyword: GORD, pH electrodes, pH monitoring

Outcome measures

Primary outcome

Acid exposure time (percentage of time with a pH below 4 at 5 cm above the upper border of the lower oesophageal sphincter)

Secondary outcome

The numbers reflux episodes detected by impedance monitoring subdivided into acid, weakly acidic and weakly alkaline reflux episodes using pH measurement.

The characteristics of the different pH electrodes (response time, sensitivity and drift)

Study description

Background summary

The acid exposure time is an important parameter that is assessed during 24-h pH-impedance monitoring in patients with gastro-oesophageal reflux disease (GORD). It is expressed as the percentage of time with a pH below the threshold of 4 in the oesophagus at 5 cm above the upper margin of the lower oesophageal sphincter (LOS). Several types of pH electrodes (glass, antimony and ISFET electrodes) are currently commercially available. It is not known whether these different types of pH electrodes will result in different acid exposure times in patients with symptoms of reflux disease.

Study objective

To compare oesophageal acid exposure time measured with glass, ISFET and antimony electrodes in patients with reflux symptoms and basic pH electrode characteristics, response time, sensitivity and drift between the 3 types of pH electrodes.

Study design

This study consists of two parts: an in vitro and an in vivo study. In the in vitro study we will assess the basic pH electrode characteristics of each type of pH electrode. For the in vivo study we will simultaneously record oesophageal pH with three different pH electrodes in each patient during an ambulatory 24h pH-impedance monitoring.

Study burden and risks

After placement, the three catheters cause no additional risk or inconvenience compared to the regular measurement with one catheter. The total diameter of the three catheters is comparable with the diameter of the catheters used during ambulatory pH-manometry in patients with non-cardiac chest pain.

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

Reflux symptoms
Age > 18y
Informed consent

Exclusion criteria

Age < 18y
Absence of Informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	23
Type:	Anticipated

Ethics review

Not approved

Date:	11-03-2008
Application type:	First submission
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	NL22155.041.08