Assessment of patients with PPI-refractory GORD: reflux monitoring with or without proton pump inhibitor?

Published: 06-10-2006
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Objective: To compare the yield of Symptom Association Probability with two approaches to investigate patients with PPI-resistant symptoms: 24-hour pH monitoring off PPI and 24-hour impedance monitoring on PPI.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON30183

Source
ToetsingOnline

Brief title
Reflux monitoring: with or without PPI?

Condition

- Gastrointestinal conditions NEC

Synonym
heartburn

Research involving
Human

Sponsors and support

Primary sponsor: St. Antonius Ziekenhuis
Source(s) of monetary or material Support: Janssen-Cilag

Intervention

Keyword: GORD, impedance-monitoring, pH-monitoring, PPI

Outcome measures

Primary outcome

Main study parameters/endpoints: For each reflux measurement the Symptom

Association Probability is calculated. Both methods will be compared according

to Bland-Altman analysis.

Secondary outcome

None

Study description

Background summary

Introduction: Excessive gastro-oesophageal reflux can lead to gastro-oesophageal reflux disease (GORD) with typical reflux symptoms such as heartburn, regurgitation and chest pain. A therapy with proton pump inhibitors will normally reduce these symptoms satisfactorily. In some patients however, symptoms are not reduced satisfactorily by PPIs.
Until recently, patients had to stop their treatment with PPI and had to perform a 24hr pH monitoring in order to observe if symptoms are related to acid reflux episodes. With impedance monitoring it is possible to detect reflux independent of the pH of the refluxate. Therefore it is possible to continue PPI therapy while performing a combined 24h pH-impedance monitoring in order to assess the association between symptoms and reflux.

Study objective

Objective: To compare the yield of Symptom Association Probability with two approaches to investigate patients with PPI-resistant symptoms: 24-hour pH monitoring off PPI and 24-hour impedance monitoring on PPI.

Study design

Study design: All patients will undergo ambulatory reflux measurement twice. First, routine manometry is used to measure the distance between the nostrils

and the upper border of the lower oesophageal sphincter. 24-h pH-metry is performed after cessation of PPIs 7 days in advance. Combined impedance-pH monitoring is performed while treatment with PPIs is continued. Patients will use a diary to note onset and type of symptom. Patients are randomised to either first measurement with or without PPIs.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participating patients will have to undergo 24h reflux monitoring twice. In daily practice, only one 24h reflux monitoring is performed. The 24h pH-impedance monitoring on PPIs is additional, but can reveal additional information that can be of benefit to the patient. This information will be communicated towards the patient*s gastroenterologist.

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

age > 18 years
typical reflux symptoms (haertburn, regurgitation, chest pain) that do not repond satisfactorily to double dose PPI-therapy

Exclusion criteria

surgery of stomach or oesophagus in patients history
condition which contraindicates the cessation of PPI therapy such as peptic ulcer disease

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-10-2006
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	06-10-2006
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-10-2006
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-02-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL13921.100.06