Tissue impedance measurement (TIM) as an index of oesophageal mucosal integrity

Published: 10-08-2011
Last updated: 30-04-2024

The primary objective of this study is to to relate bio-impedance findings with microscopically measured intercellular spaces inoesophageal epithelium.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational invasive

Summary

ID

NL-OMON34180

Source
ToetsingOnline

Brief title
Tissue impedance measurement (TIM): index of oesophageal mucosal integrity

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
gastro-oesophageal reflux disease, reflux

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: Intercellular space, mucosal integrity, oesophagus, Tissue impedance measurement

Outcome measures

Primary outcome

To correlate tissue impedance, expressed in Ohm, and degree of dilation of

intercellular spaces with electron microscopy.

Secondary outcome

Not applicable.

Study description

Background summary

In the past few decades, understanding has grown substantially about gastroesophageal reflux disease (GERD). The disease is caused by reflux of noxious gastric content upwards into the oesophagus. The disease is common and affects an estimated 20% of the population. Complaints consist of heartburn, regurgitation, and chest pain. Amongst the normal work-up in these patients an endoscopy is performed. According to the macroscopic findings during this procedure, patients can be divided into two distinct categories. The first group has macroscopic abnormalities of the oesophagus, presumably caused by the refluxate, and is categorized as having erosive reflux disease (30-40%, ERD). The second group shows no abnormalities and is classified as non-erosive reflux disease (60-70%, NERD).
Although medical treatment with proton pump inhibitors (PPI*s) offer excellent results and will provide healing of erosions in 85-95%, a large proportion of patients (up to 40%) do not obtain symptom relief. Renewed endoscopy in these patients is not useful as this will not discriminate between either NERD and ERD with healed erosions, or between NERD and non-GERD related problems (such as functional causes). In order to be able to differentiate between these groups without the need for routine histological examination, a new tool has been developed. Tissue impedance measurement (TIM) is able, in theory at

least, to determine microscopic damage to the mucosa by way of detecting an increase in intercellular spaces. The present pilot
study aims to evaluate the feasibility of applying TIM in a clinical examination and to relate bio-impedance findings with microscopically measured intercellular spaces in oesophageal epithelium in normal subjects.

Study objective

The primary objective of this study is to to relate bio-impedance findings with microscopically measured intercellular spaces in
oesophageal epithelium.

Study design

Observational study.

Study burden and risks

Participants will undergo several routine investigations, such as ECG, blood tests and an endoscopy. During the endoscopy, a probe will be placed adjacent to the mucosa of the oesophagus and biopsies will be taken. No specific risk is associated with
these investigations. However, introduction of the scope van cause irritation of the throat and sometimes results in vomiting. In general, as soon as the scope is in place, little inconvenience is noted. Generally, a gastroscopy is seen as a burdon. After gastroscopy, a sore throat may be noted. This soon disappears. In addition, biopsies are taken of the oesophagus. This is associated with the risk of continuous bleeding afterwards. In such a specific case, additional treatment would be carried out. The injection of midazolam is associated with a deminished breathing volume and breathing velocity as well as changes in blood pressure and heart rate. Also, haedaches can occur. Rarely, pain at the site of injection of hypersensitivity reactions occur.

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

* Females and males between 18 and 45 yrs of age
* No significant clinical pathology or history of heartburn, regurgitation, dysphagia or chest pain or acid
suppressive therapy or any other major abdominal complaints in the last year. No history of signs of pathological
changes of the oesophageal mucosa visible with conventional endoscopic examination
* BMI < 30 or a body weight < 100 kg
* No clinically significant illness within the 2 weeks prior to inclusion or a suspected/manifest infection according
to WHO risk categories 2, 3 or 4, as judged by the investigator
* No history of clinically significant illness, cardiovascular, respiratory, renal, hepatic, neurological, mental or
gastrointestinal, as judged by the investigator
* Normal ECG as judged by the investigator
* Absence of severe allergy/hypersensitivity or symptoms/signs of ongoing allergy/hypersensivity
* No history of excessive bleeding or suspected coagulopathy
* No prior surgery of the upper GI tract except over sewing of an ulcer
* No use of PPI, H2 receptor antagonists, pro-kinetic drugs or need for any medication for gastroesophageal
reflux disease
* No history of drug addiction (including cannabinoids), alcohol abuse or other circumstances which in the investigator*s judgment may compromise the subject*s participation
* No involvement in the planning and conduct of the study

* No pregnancy or lactation
* Signed informed consent to participate in the study

Exclusion criteria

* Clinically significant illness within the 2 weeks prior to inclusion or a suspected/manifest infection according to
WHO risk categories 2, 3 or 4, as judged by the investigator
* Absence of informed consent
* BMI *30 or a body weight * 100 kg
* History of clinically significant illness, cardiovascular, respiratory, renal, hepatic, neurological, mental or
gastrointestinal, as judged by the investigator
* Abnormal ECG as judged by the investigator
* History of severe allergy/hypersensitivity or symptoms/signs of ongoing allergy/hypersensivity
* History of excessive bleeding or suspected coagulopathy
* Prior surgery of the upper GI tract except over sewing of an ulcer
* Use of PPI, H2 receptor antagonists, pro-kinetic drugs or need for any medication for gastroesophageal reflux
disease
* History of drug addiction (including cannabinoids), alcohol abuse or other circumstances which in the
investigator*s judgment may compromise the subject*s participation
* Inability to comply with study procedures
* Involvement in the planning and conduct of the study
* Previous enrolment in the present study.
* Pregnancy or lactation

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:	15
Type:	Anticipated

Ethics review

Approved WMO Date:	10-08-2011
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	NL32608.041.10