Evaluation of the WavSTAT Optical Biopsy System for the detection of early neoplasia in the Barrett oesophagus

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1. to investigate the WavSTAT optical biopsy system by collecting fluorescence spectra of non-dysplastic and dysplastic Barrett mucosa and correlate these to the histology. The integrated optical/physical biopsy forceps will ensure spot-on...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON35892

Source
ToetsingOnline

Brief title
WavSTAT study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
1) Barrett oesophagus, 2) early oesophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Barrett, neoplasia., oesophagus, spectroscopy

Outcome measures

Primary outcome

Phase 1 will be used to develop a tissue recognition algorithm by correlating

the measured fluorescence spectra to the histology of the corresponding tissue.

In phase 2 the WavSTAT optical biopsy will be validated and assessed for the

following outcome parameters:

1. sensitivity and specificity of WavSTAT for the detection of early Barrett

neoplasia (HGIN/EC)

2. additional value of WavSTAT to standard inspection with WLE, compared to

inspection with WLE alone for the detection of early Barrett neoplasia

(HGIN/EC).

Secondary outcome

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Study description

Background summary

In patients with Barrett oesophagus (BO) malignant degeneration may occur through a series of phenotypic cellular changes detected and graded on microscopy; beginning with non-dysplastic intestinal metaplasia (IM), then low- (LGIN) and high-grade intraepithelial neoplasia (HGIN), and eventually early cancer (EC) may arise1,2. Endoscopic surveillance of patients with BO is, therefore, recommended to detect early neoplasia at a curable stage3. When using standard endoscopy, however, it may be difficult to distinguish areas with early neoplasia (i.e. HGIN a/o EC) within the normal Barrett mucosa4.

Thus, in the absence of visible abnormalities random four-quadrant biopsies are obtained every 1-2 cm of the BO, to allow for histological evaluation for the presence of neoplasia (Seattle protocol)4,5. But, random biopsies are associated with a high rate of sampling error and may miss malignant lesions in the BO6. Moreover, the extensive biopsy protocol poses significant burden on the patient, the endoscopist and the health care system, due to prolonged endoscopy time and high costs.

To increase the detection rate of early neoplasia during endoscopic surveillance of BO patients, different imaging techniques have been developed. In this respect, roughly two imaging goals have to be distinguished: first and foremost, suspicious lesions will have to be identified in the BO, which requires a *red flag* imaging modality with the ability to draw attention to a certain area of interest. Second, a differentiating tool will have to be able to distinguish between truly suspicious areas (i.e. HGIN/EC) or false positive areas.

The interaction between tissue and light has been studies extensively. When light of certain wavelength is emitted on tissue, four events characterize the physical course of the light: reflection, absorption, scattering and fluorescence. When an incoming photon hits a fluorescent molecule (fluorophore), an electron gets excited, after which it relaxes back into a lower energy status. A part of the energy is thus absorbed, and the molecule emits a photon of lower energy and longer wavelength7. Influenced by physiological and pathophysiological fluctuations in biochemistry and structure, each tissue has a distinct fluorescent spectral signature. Normal oesophageal tissue, Barrett metaplasia and dysplasia have a measurable different spectral signature, suitable for integration in a diagnostic system using spectroscopy8. In this way, spectroscopy might be used as a differentiating tool to distinguish between dysplastic and non-dysplastic tissue.

Probe based spectroscopy is a technique utilizing excitation light of a single, short wavelength, delivered to the tissue through an optical fiber, after which the emitted light is collected by the same fiber and passed to a spectrometer. The signal is then transferred to a computer and analyzed. The optical fiber can be passed through an endoscope, allowing for in-vivo spectroscopy in patients with BO.

The WavSTAT optical biopsy system comprises an optical fiber, integrated in a modified standard biopsy forceps, which is connected to a processing system with a spectrometer, computer and user-interface console. The WavSTAT system allows for real-time, in-vivo spectroscopic measurements (optical biopsy) and provides spot-on correlation with the histology of the corresponding physical biopsy.

We therefore hypothesize that the WavSTAT optical biopsy system may improve the endoscopists ability to detect and distinguish suspicious lesions in the BO, while reducing the need for extensive biopsy protocols during surveillance endoscopies.

Study objective

1. to investigate the WavSTAT optical biopsy system by collecting fluorescence spectra of non-dysplastic and dysplastic Barrett mucosa and correlate these to the histology. The integrated optical/physical biopsy forceps will ensure spot-on correlation. The results of this study will be used to develop a differentiating, tissue recognition algorithm.
2. In a second validation study, the algorithm is integrated in the system and patients with a Barrett oesophagus will be investigated by standard white light endoscopy and with the WavSTAT optical biopsy system to assess the additional value of this differentiation tool for the detection of early neoplasia in BO.

Study design

The study will be conducted in two distinct phases:

phase 1) 20 patients with a Barrett oesophagus (15 patients with HGIN/EC and 5 with non dysplastic Barrett oesophagus (NDBO)) will be included. During the endoscopy, the oesophagus will be inspected in detail with standard white light endoscopy. Suspicious areas will be recorded and imaged, after which spectroscopic measurements will be performed using the WavSTAT optical biopsy forceps, followed by correlating biopsies with the same WavSTAT biopsy forceps. This ensures spot-on correlation between the measured spectra and the corresponding histology. After this, random biopsies will be obtained with the WavSTAT system. The collected data will be used to develop a distinguishing algorithm, which will be integrated into the WavSTAT system.

phase 2) 150 patients with a Barrett oesophagus referred for work-up and treatment of HGIN and EC will be included. The endoscopic procedures are equal to phase 1. In phase 2, the algorithm will be validated and the additional and predictive value of WavSTAT over standard endoscopy alone assessed.

Study burden and risks

The WavSTAT Optical Biopsy System is non-invasive in nature. The type of light delivered by the optical fiber is equivalent in intensity to the standard light source used and delivered by a standard endoscope; the excitation of tissue by the light energy delivered by the optical biopsy system is non-damaging and does not result in any thermal effects on tissue. The collection of physical tissue biopsies in these subjects is standard part of the procedure for surveillance or work-up endoscopies for Barrett oesophagus, with minimal potential risk to the health, safety or welfare of the subject. All tissue biopsies taken as part of this study will be part of the standard of care. Enrollment in the study will not affect in any way the subject*s diagnosis, treatment or mitigation of any identified disease.
Due to the spectroscopies prior to the collection of physical biopsies, the

endoscopy will take 10 minutes longer than usual.

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 * 80 years;
- BO with a minimal circumferential length of 2 cm;
- BO without dysplasia (NDBO) and patients with BO referred for endoscopic work-up of HGIN or EC;
- Signed informed consent.

Exclusion criteria

- Prior history of surgical or endoscopic treatment for oesophageal neoplasia;
- Presence of erosive oesophagitis (Los Angeles classification *B);
- Inability to obtain biopsies (e.g. due to anticoagulation, coagulation disorders, varices);
- Unable to provide signed informed consent.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2011
Enrollment:	129
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
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	NL36225.018.11