High Resolution Optical Imaging of Barrett*s Esophagus Using N-Vision pVLE

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In patients undergoing surveillance endoscopy for Barrett;s oesophagus or work-up and treatment for early neoplasia in Barrett's oesophagus we will evaluate the N-Vision pVLE system for the following items:1) feasibility of the system2) the...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON37408

Source
ToetsingOnline

Brief title
N-Vision

Condition

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

Synonym
1) Barrett's 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: advanced imaging, Barrett's oesophagus, early neoplasia

Outcome measures

Primary outcome

Phase 1

1) feasibility of the system

2) the capacity of the system to construct a high-resolution map of the mucosal lining of the oesophagus

3) the capacity of detecting areas suspicious for neoplasia (by correlating the suspicious areas identified by the N-Vision system to the histological diagnosis of the biopsy specimen of that particular area).

Phase 2

1) sensitivity and specificity of the pVLE system for the detection of early neoplasia in BE

2) additional value of the pVLE system over the assessment of the endoscopist alone.

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. However, 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 N-Vision pVLE system is a newly developed diagnostic tool that will allow high resolution imaging of the oesophageal mucosa through Optical Frequency Domain Imaging (OFDI), a second generation Optical Coherence Tomography (OCT) technology. OFDI compares backscattered light from tissue to a reference signal, which allows high resolution depth resolved imaging of the investigated tissue. In essence, OFDI is a kind of optical ultrasound imaging. The N-Vision probe based Volumetric Laser Endomicroscopy (pVLE) system incorporates OFDI in a rotating endoscopic probe, that allows for real-time, 3D high resolution imaging of the oesophageal mucosa. The N-Vision system can be used as an additional tool during standard surveillance endoscopy for Barrett's oesophagus or work-up of early neoplasia. The 3D mucosal map that is projected on the screen of the n-Vision system may identify suspicious areas that would otherwise have been overlooked by standard white light endoscopy.

Study objective

In patients undergoing surveillance endoscopy for Barrett;s oesophagus or work-up and treatment for early neoplasia in Barrett's oesophagus we will evaluate the N-Vision pVLE system for the following items:
1) feasibility of the system
2) the capacity of the system to construct a high-resolution map of the mucosal lining of the oesophagus

3) the capacity of detecting areas suspicious for neoplasia (by correlating the suspicious areas identified by the N-Vision system to the histological diagnosis of the biopsy specimen of that particular area).

Study design

In phase 1, 50 patients will be included in this study: 30 patients with a Barrett's oesophagus without early neoplasia and 20 patients with early neoplasia arising of Barrett's oesophagus.
During standard endoscopy for surveillance or work-up, the oesophagus will first be examined with white light endoscopy, recording all marks, distances and possible suspicious areas. Subsequently, the N-Vision probe will be deployed through the working channel of the endoscope, the balloon inflated and the inner lining of the oesophagus imaged. Areas suspicious for early neoplasia identified on the N-Vision 3D image will be recorded.
Mapping with the N-Vision is followed by standard biopsies: all suspicious areas and random four-quadrant biopsies, as required by the official guidelines. All histological evaluation is done by both a junior and a senior pathologist. All histology will be reviewed by a GI-expert pathologist. The histological data will be correlated to the N-Vision data.

Study burden and risks

The N-Vision pVLE 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 imaging with the N-Vision pVLE system prior to the collection of physical biopsies, the endoscopy will take 15 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 over 18 years
- patients referred with Barrett's oesophagus with and without early neoplasia
- written informed consent

Exclusion criteria

- patients with a condition precluding full distension of the N-Vision balloon, such as strictures or a mass
- inability to obtain biopsies (e.g. due to antocoagulation therapie, coagulation disorder, varices)
- eosophillic oesophagitis
- pregnancy
- 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:	Will not start
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Date:	22-08-2012
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	NL38360.018.12