Feasibility of Computer guided Volumetric Laser Endomicroscopy (VLE) Targeted Biopsies for Improved Detection of Early Barrett*s Neoplasia

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

Summary

ID

NL-OMON48059

Source
ToetsingOnline

Brief title
VLE CAD pilot study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Barrett's esophagus, early esophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Health Holland via TKI-toeslag,NinePoint

Medical,Technische Universiteit Eindhoven

Intervention

Keyword: Barrett neoplasia, Computer algorithm, Volumetric laser endomicroscopy

Outcome measures

Primary outcome

a) Can the suspicious regions of interest, which are predicted by VLE-CAD, be

targeted by laser marking?

Questionnaire analysis using Likert scale: 1-5

b) Feasibility of workflow? Questionnaire analysis using Likert scale: 1-5

Secondary outcome

a) Diagnostic performance of CAD targeted biopsies (sensitivity, specificity)

b) Proportion of VLE-CAD guided biopsies positive for dysplasia, assessed at a

per biopsy & per patient level

c) Safety

- Number of (serious) adverse events related to VLE-CAD guided biopsies

d) VLE procedure time, including image acquisition and targeting, not including

time for biopsy or resection.

e) Total number of VLE-CAD guided biopsies per patient

Study description

Background summary

Esophageal cancer (adenocarcinoma) is a amongst the deadliest cancers, with 5-year survival rates <15%. The incidence of esophageal cancer has rised rapidly over the last decades. Patients with a condition called Barretts esophagus are at increased risk of developing adenocarcinoma.
In BE the normal lining of squamous epithelium is replaced by metaplastic columnar epithelium. BE is caused by gastrointestinal! acid reflux.

The estimated prevalence of BE in Europe is 1.6 per 100 people. The progression to EAC develops through a stepwise process from BE to low-grade and high-grade dysplasia, and eventually to EAC. Therefore, the standard of care for Barrett's patients consists of regular surveillance with white-light endoscopy and quadrantic random biopsies every two centimeter of the Barrett's segment, to detect neoplasia in an early stage.

The current surveillance protocol is, however, hindered by several difficulties. First, early esophageal neoplastic lesions are associated with only subtte mucosa! changes and therefore difficult to detect upon white-light endoscopy. The random biopsies one sample a small part of the Barrett segment, leading to sample error. Third the current protocol is labarous and a burder for the patient and the health care system.

The solution to improve the current surveillance protocol lies in enabling better visualization of early neopltasia in BE, thereby increasing detection rates. Volumetric Laser Endomicroscopy (VLE) is a system that enables 3D scanning of the esophagus during an endoscopic procedure, showing subsurface irregularities that are invisible during endoscopy. Furthermore, with the new VLE laser marking system, suspicious area can directly be marked. This might enable to take targeted biopsies in the future, instead of numerous random biopsies. This will imrpove the current surveillance protocol.

Interpretation of a VLE scan, harboring a large amount of data, with the human eye is complex. Therefore, the addition of a computer-assisted BE neoplasia detection algorithm for VLE could further enhance the potential of the system to improve BE surveillance.

Study objective

The aim of this study is to test the feasibility of a VLE computer algorith that could improve detection of early neoplasie in BE patients.

Study design

This study will be conducted at the Departments of Gastroenterology and Hepatology of the Amsterdam AMC, location AMC/VUmc, the Catharina Hospital Eindhoven, and St. Antonius Nieuwegein en de Videocoding group at the technical university of Eindhoven.
The study consists of the following parts:

1) Performing a VLE scan during the endoscopy
2) Test the feasibility and its workflow of the computer algorithm for VLE, for the detection of BE neoplasia.

Study burden and risks

Previous studies, of which one was conducted at the AMC (METC 2015_244, METC_122) have evaluated the VLE laser marking system and found that the system was feasible and safe. The NVision VLE System is non-invasive in nature. The type of light delivered by the optical probe 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 expandable balloon of the guide sheath has the potential of causing lacerations or * in very rare occasions * perforation of the esophagus when inflated above maximum allowed pressure. A safety valve is included in the design ofthe balloon to avoid this problem. In patients with an esophageal stricture, the risk of laceration increases, and these patients are therefore excluded from participation in this trial. The endoscopic procedure will take an estimated 30-60 minutes (estimated average 45 minutes) longer compared to the standard endoscopy.

The VLE procedure is not expected to produce any additional discomfort or unique risks to the subject as compared to those already associated with endoscopy and biopsy.

The marking laser will have similar risks as the placement cautery marks with the tip of an endoscopic snare, that is used in clinical setting to mark areas or to delineate lesions. The risks of bleeding or perforation from marking the site are minimal. The laser marks on the esophageal tissue will not affect histopathological diagnosis, as the use of cautery marking in clinical setting for delineation of lesions didn't affect histopathological diagnosis.

Below a brief summary is given of potential risks when using the NVision VLE system. For extensive description, we direct you to the protocol, sections Device Information and Structured Risk Analysis.

The NvisionVLE Imaging System contains two laser systems, one for imaging and a second optional for marking tissue. The imaging laser is classified as Class 1M, while the marking laser is classified as a Class 4 Laser Product. Light energy emitted by the NinePoint Medical! NvisionVLE Imaging System lies in the

invisible, near-infrared region of the electromagnetic spectrum. It cannot be seen with the naked eye. Inadvertent exposure to laser light may cause skin or eye damage. Precautions will be made to ensure that the optical probe portion of the Optical Probe is inside the endoscope prior to transmitting laser energy through the system. Laser energy can be transmitted during self-test, during scanning (Ful! or Scout Scan) or marking (Manual Scan). Viewing the laser output with certain optical instruments (for example eye loupes, magnifiers, and microscopes) within a distance of 100 mm may pose an eye hazard. During imaging, laser safety eyewear is not required. During laser marking, additional safety steps must be taken (please see protocol). Warning: Always ensure the distal end ofthe Optical Probe has been inserted into the body or an endoscope prior to activating laser. Never look directly into the laser beam coming from the system or reflected from a surface. Electrical and Mechanical Hazards: When the exterior housing of the NvisionVLE Imaging System is not displaced, there is no risk from high voltage risks from inside the system. Movement of the system has to be done carefully and slowly. To reduce the risk of electric shock, do not connect the system's input power connection to equipment that is not protectively earth grounded. The participating expert endoscopists, research nurses and researchers will receive training on the Nvision VLE marking system prior to use.

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;
* Ability to provide written, informed consent (approved by IRB) and understand the responsibilities of trial participation.
* Minimum Barrett*s extent (from Prague criteria) M * 2cm;
* Known BE, defined as columnar lined epithelium of the esophagus containing intestinal metaplasia upon biopsy, with or without dysplasia (low-grade or high-grade dysplasia or early adenocarcinoma);

Exclusion criteria

* Presence of an esophageal mass that precludes full distention of the balloon from the NvisionVLE Optical Probe;
* Patients with known esophageal strictures, esophageal tears or ulcers, which would prohibit full distention of the balloon from the NvisionVLE Optical Probe;
* Contraindications for endomucosal resection (EMR) and/or obtaining biopsies (e.g. due to anticoagulation, coagulation disorders, esophageal varices);
* Patients within four weeks of receiving targeted forceps biopsies and/or EMR;
* 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:	18
Type:	Anticipated

Medical products/devices used

Generic name:	Nvision VLE Imaging System with Nvision VLE marking Probe
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-10-2019
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	NL70672.018.19