Pilot Feasibility Study: Laser Marking Using the NvisionVLE® Imaging System

Published: 02-11-2015
Last updated: 19-04-2024

Primary objectiveThe primary objective of this trial is to determine the visibility and positional accuracy of laser marks applied by the NvisionVLE Imaging System.

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

Summary

ID

NL-OMON42384

Source
ToetsingOnline

Brief title
VLE laser marking

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Barrett's esophagus, early esophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Ninepoint Medical
Source(s) of monetary or material Support: Ninepoint Medical

Intervention

Keyword: Barrett's neoplasia, early detection, laser marking, Volumetric laser

endomicroscopy

Outcome measures

Primary outcome

Primary outcome measures

* Percentage of laser marks visible to the physician using WLE (white light

endoscopy) and VLE

* Positional accuracy of laser marks

Secondary outcome

Secundary outcome measures

* All adverse events will be collected and analyzed.

Study description

Background summary

When using standard endoscopy it may be difficult to distinguish areas with early neoplasia (i.e. HGIN a/o EC) within the normal Barrett mucosa. Therefore, in the absence of visible abnormalities, random biopsies are obtained of the Barrett*s esophagus, to allow for histological evaluation for the presence of neoplasia. Optical Frequency Domain Imaging (OFDI) is an imaging modality that may have the ability to improve the current paradigm for endoscopic screening and surveillance. OFDI can be thought of as an analogous technique to ultrasound, but with light instead of sound waves. OFDI was incorporated in a probe-based system for easy, through the scope access to the esophagus lumen: Volumetric laser endomicroscopy (VLE). VLE enables imaging of large, continuous, areas of the esophagus, up to 38 cm2 per scan, with microscopic resolution. This technique may improve the efficiency of surveillance of Barrett*s esophagus. Furthermore, the number of random biopsies may be decreased, which could reduce procedure time, -costs and -burden.
This study examines an additional tool of the VLE system: the laser marking system. Suspicious areas identified in the VLE scan need to be accurately located on the esophageal surface to allow the physician to acquire tissue or guide therapy to those locations. The laser marking system is capable of applying a directed superficial cautery mark on the mucosal surface of the esophagus.

The rationale for this study is to assess the visibility and positional accuracy of the laser marks. Ongoing VLE studies in our center are examining the ability of VLE to differentiate dysplasia from non-dysplastic Barrett*s using VLE images correlated to histology. Combined with VLE imagery, the targeting enabled by the laser marking system could have the potential to increase the diagnostic accuracy of current surveillance protocols, to guide interventional treatments such as the delineation of margins for mucosal resection, and to allow direct registration of the endomicroscopy images obtained by VLE with the resulting histopathology. In the future these advances could positively impact the management of patients with BE by extending surveillance intervals, enabling minimally invasive endoscopic techniques at an earlier stage of disease and preventing unnecessary esophagectomy.

Study objective

Primary objective
The primary objective of this trial is to determine the visibility and positional accuracy of laser marks applied by the NvisionVLE Imaging System.

Study design

This is a prospective, single-site trial including two phases:
1.) *Learning Phase* - Two patients will be enrolled to optimize procedural workflow.
2.) The second phase will include 15 patients.

Study burden and risks

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 of the 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.
This study will evaluate the use of the marking laser (IPG Photonics * 3W Raman Laser), which is coupled to the NvisionVLE Imaging System. The trial will also evaluate the use a new Hand Controller which is attached to the endoscope (see page 9, 10). 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. In a previous study by our group, tissue

was marked using the tip of an endoscopic snare with coagulation current (these cautery marks are the standard procedure for example for delineation of lesions) (11). No marking-related adverse events were noted when using cautery marks. The marking laser will have similar risks as the cautery marks. 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.

Potential adverse events/risks
Below a brief summary is given of potential risks when using the NVision VLE system. The full text is provided in the Appendix on page 33 and onwards. In addition the document *NvisionVLE Operators Manual (Clinical)_9sep015* is provided with an entire overview of the system (chapter 5 contains the Risks section). Secondly, an extensive document on marking laser engineering safety controls of the system is available describing all safety measures incorporated in the system to ensure safety of the patient and all co-operators working with and in the room with the laser marking device (see table 2 in Appendix, page 25 onwards).

Optical Hazards:
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 (Full 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 Appendix, page 33):
Warning: Always ensure the distal end of the 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.

Previous laser marking studies
Several previous studies have been conducted with the laser marking system

whereby safety issues were being addressed. Please find a summary on page 3 of this protocol and for a complete overview Preliminary laser marking studies in the Appendix (page 17 onwards). The current study is the logical next step following the results of the preliminary studies.

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

Inclusion criteria
* Patients over the age of 18
* Patients undergoing an upper endoscopy for Barrett surveillance with prior confirmed BE,

with or without neoplasia.
* Ability to provide written, informed consent.
* Women of childbearing potential must be willing to take a pregnancy test.;Exclusion criteria
* Presence of an esophageal mass that precludes full distention of the balloon from the NvisionVLE Optical Probe.
* Patients with esophageal strictures that would prevent adequate expansion of the balloon from the NvisionVLE Optical Probe.
* Patients with known inflammatory disease, esophageal tears or ulcers, which would prohibit full distention of the balloon from the NvisionVLE Optical Probe.
* Patients who are pregnant.
* Patients with a history of hemostasis disorders*.
* Hemostasis disorders will include, but will not be limited to: patients with hemophilia or other congenitally acquired clotting factor deficiencies, patients with cirrhosis with coagulopathy, patients known to have thrombocytopenia (<100,000 plt/ul) and individuals with von Willibrand*s disease or other known platelet malfunction disorders.

Exclusion criteria

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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):	29-01-2016
Enrollment:	17
Type:	Actual

Medical products/devices used

Generic name:	NvisionVLE® Imaging System with NvisionVLE Marking Probe
Registration:	No

Ethics review

Approved WMO Date:	02-11-2015
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	NL54925.018.15