A Comparison of Volumetric Laser Endomicroscopy (VLE) and Endoscopic Mucosal Resection (EMR) in Patients with Barrett's Dysplasia or Intramucosal Adenocarcinoma

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Positief advies
Werving gestart
-
Interventie onderzoek

Samenvatting

ID

NL-OMON29133

Bron NTR

Verkorte titel nVision EMR

Aandoening

Barrett's esophagus early neoplasia advanced imaging

Barrett slokdarm vroege neoplasie

Ondersteuning

Primaire sponsor: AMC Amsterdam

Overige ondersteuning: Ninepoint Medical

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint will be the correlation of features seen on VLE images to those seen on histopathology from mucosal resection specimens.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

In patients with Barrett oesophagus (BO) malignant degeneration may occur through a series of phenotypic cellular changes detected and graded on microscopy; beginning with nondysplastic 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-guadrant 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. VLE is a new technique. Before it can be applied in the clinic, VLE imaging needs to be validated. Therefore, the VLE images have to be correlated to the histopathological features of the imaged tissue. A standardized, ex-vivo set-up will ensure spot-on correlation between the VLE images and the imaged tissue.

Objective of the study:

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) Correlating the VLE images with the corresponding histology of the biopsy specimen of Barrett's neoplasia in the oesophagus and in the endoscopic biopsy specimen. 2) Correlating the VLE images with the corresponding histology of the biopsy specimen. 3) To define VLE image characteristics and develope a VLE classification system for the imaging of Barrett's oesophagus. 4) To creating a VLE imaging atlas with corresponding histology. 5) To optimize and validate the VLE classification by independent observers.

Study design:

Endoscopic procedure: 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-guadrant biopsies, as required by the official guidelines. The endoscopist will remove the system after performing this. If there is an abnormality, this will be marked by electrocoagulation according to the guidelines, followed by endoscopic resection of the abnormality by the Cap-technique according to the guidelines. When indicated, biopsies will follow of other (suspected) abnormalities. All abnormalities will be visualised with the N-Vision VLE system. After the procedure the biopsy specimen will be placed in an especially constructed mold and the second pVLE imaging will take place. Afterwards diagnostic work up will be done on the specimen by the pathology department. 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. These images and histology results will be used to create an image atlas and to develop and validate a VLE classification system for imaging and reviewing Barrett's mucosa and neoplasia in the oesophagus. The study will be done in 2 phases: 1) First phase is a singlecentre pilot study, in which set up and logistics of the system will be optimalised, the VLE

3 - A Comparison of Volumetric Laser Endomicroscopy (VLE) and Endoscopic Mucosal Res ... 5-05-2025

image characteristics will be defined and the VLE classification determined. In this phase,10 patients will be included: 5 patients with Barrett's oesophagus without dysplasia and 5 patients with an early neoplastic abnormality of Barrett's oesophagus. 2) In the second phase, 100 patients will be included in 5 centres; 20 patients per centre of which 5 with non-dysplastic Barrett patients and 15 patients with an early neoplastic abnormality of Barrett's oesophagus. In this phase, the image-atlas will be created and the VLE classification optimized and validated by indepent observers.

Doel van het onderzoek

The nVision pVLE system may be able to generate real-time, high-resolution mucosal maps of a large surface area of the esophagus, which may aid the endoscopist during surveillance endoscopy in real-time detection of suspicious lesions in patients with Barrett's esophagus.

Onderzoeksopzet

VLE scanning takes place once in patients with a suspected neoplastic lesion. No other timepoints are applicable.

Onderzoeksproduct en/of interventie

The study uses the VLE catheter to examine and scan the distal Barrett's esophagus. VLE is an advanced imaging technique that has the potential to better visualize early neoplasia in Barrett's esophagus. This technique however, has not been validated yet, so in this study we're aiming to do so by performing one-on-one correlation of the VLE images with the corresponding histology from the EMR's. VLE, in other words, is not a treatment but a diagnostic technique. The intervention is that the balloon (containing the VLE catheter) will be guided through the working channel of the endoscope and will be brought into the distal esophagus where scanning is performed. These scan(s) take about 2 minutes each and 1-4 scans per patient will be performed, depending of scanning results. The procedure will take about 15-20 minutes longer than normal. After scanning an EMR is done to obtain the histological substrate of the VLE scans in-vivo as well as ex-vivo of the EMR specimen. There are two groups of patients: non-dysplastic Barrett's and dysplastic Barrett's. This way we can validate VLE in non-dysplastic Barrett's and dysplastic Barrett's.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Males and females over the age of 18 years;

2. Patients with either suspected or confirmed Barrett's-associated dysplasia or intramucosal adenocarcinoma presenting for endoscopy likely requiring EMR;

- 3. Patients with non-dysplastic Barrett's oesophagus;
- 4. Eligible for endoscopic resection of Barrett mucosa;
- 5. Ability to provide written, informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with a condition precluding full distension of the N-Vision balloon, such as strictures or a mass;

2. Inability to obtain biopsies and/or EMR (e.g. due to antocoagulation therapie, coagulation disorder, varices);

- 3. Eosophillic oesophagitis;
- 4. Oesophagitis > LA grade A;
- 5. Pregnancy;
 - 5 A Comparison of Volumetric Laser Endomicroscopy (VLE) and Endoscopic Mucosal Res ... 5-05-2025

6. Unable to provide signed informed consent.

Onderzoeksopzet

Opzet

Туре:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	10-05-2013
Aantal proefpersonen:	110
Туре:	Verwachte startdatum

Ethische beoordeling

Positief advies Datum: Soort:

01-07-2013 Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3893
NTR-old	NTR4055
Ander register	NL43663.018.13 : MEC 2013/027
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten N/A