THE VALUE OF AUTOFLUORESCENCE ENDOSCOPY FOR THE DETECTION OF EARLY BARRETT*S CANCER

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To compare the yield of autofluorescence guided targeted biopsy versus four-quadrant random biopsy in the evaluation of patients with known occult neoplastic lesions in Barrett*s Esophagus.

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

Summary

ID

NL-OMON32071

Source
ToetsingOnline

Brief title
ABC study

Condition

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

Synonym
Barrett's cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: autofluorescence endoscopy, Barrett esophagus, detection, Early carcinoma, high grade dysplasia

Outcome measures

Primary outcome

The number of detected HGD/EC lesions in Barrett*s Esophagus in the FQRB by use

of video endoscopy compared to the number of detected lesion by the

autofluorescence guided targeted biopsy specimens.

Secondary outcome

1) The number of biopsy specimens needed to detect one HGD/EC lesion by the use

of AFE guided biopsy specimens.

2) The number of biopsy specimens needed to detect one HGD/EC lesion by the use

of video endoscopy FQRB.

3) Duration of the procedure for WLE, AF endoscopy and video endoscopy.

Study description

Background summary

Many centers recommend endoscopic surveillance for patients with BE to detect Barrett*s neoplasia at an early, curable stage. It has been estimated that early detection of esophageal adenocarcinoma, using endoscopic surveillance regimens, can improve the cure rates from 20 to 76 %. The current gold standard for endoscopic surveillance of BE entails taking biopsy specimens from each endoscopically visible mucosal abnormality followed by random 4-quadrant biopsies every 2 cm throughout the length of the BE, beginning at the proximal end of the gastric folds proximally to the esophageal mucosa.
Random biopsy sampling with a conventional white-light endoscope is time consuming, and is subject to a sampling error.Other endoscopic techniques are currently under investigation to improve detection of early lesions, primarily through targeting of biopsy sampling. High - resolution endoscopy has shown to be sensitive for the visualisation of early mucosal abnormalities. However,

even with the most advanced endoscopes, high-grade dysplasia or early carcinoma is not always visible in the esophageal mucosa and the risk for undetected dysplastic or malignant lesions is still present.
Autofluorescence endoscopy (AFE) is based on the presence of endogenous molecules (fluorophores) such as collagen, nicotinamide adenine dinucleotide, and porphyrins, in the mucosa. These molecules can emit fluorescence light of a longer wavelength when excited with short- wavelength light (typically blue light).Tissue alterations as in neoplasia may change the concentration and spatial distribution of the various endogenous fluorophores and consequently alter the tissue autofluorescence.AFE enables rapid screening of large surface areas of mucosa and has been shown to improve detection of dysplastic lesions in the colon, especially small lesions, early stage lesions and flat or depressed adenomas. Application of AFE in screening of Barrett*s mucosa has so far been limited by a high rate of false- positive findings, which is probably due to changes attributable to active inflammation.However, published studies evaluating the value of autofluorescence endoscopy in the detection of early esophageal neoplasia have been performed with a video AFE system that is less sensitive for the weak autofluorescence signal than our AFE system.

Study objective

To compare the yield of autofluorescence guided targeted biopsy versus four-quadrant random biopsy in the evaluation of patients with known occult neoplastic lesions in Barrett*s Esophagus.

Study design

page 3 protocol: flow chart

Study burden and risks

Esophagoscopy is considered to be a low risk intervention

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

Patients age >= 18 years scheduled for endoscopy because of recently diagnosed random HGD/EC lesions in Barrett*s Esophagus.

Exclusion criteria

* Patients unable or unwilling to give informed consent
* Coagulopathy uncorrected at the time of endoscopy or thrombocytopenia (<50 x 109 / l thrombocytes)
* Patients with active reflux esophagitis

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2008
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	24-04-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL21543.078.08