Endoscopic Tri-Modal Imaging (ETMI) for the detection of early neoplasia in patients with Barrett*s esophagus (BE) in tertiary referral centers; a randomized cross-over multi-center study.

Published: 23-01-2007
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Does ETMI improve the dysplasia in Barrett's esophagus?

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

Summary

ID

NL-OMON30430

Source
ToetsingOnline

Brief title
ETMIcross

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Barrett's esophagus, esophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,Olympus, Japan,Olympus;Japan

Intervention

Keyword: Autofluorescence, Barrett's esophagus, Early neoplasia, Narrow Band Imaging

Outcome measures

Primary outcome

Number of patients detected with dysplasia.

Number of lesions detected with dysplasia.

Secondary outcome

Positive predictive value of high-resolution white light endoscopy and

autofluorescence imaging.

Reduction of fals-positive findingfs with narrow band imaging.

Study description

Background summary

Barrett's esophagus is a premalignant disease. Dysplastic change occur in a sequential order from low garde dysplasia - high grade dysplasia - intramucosal carcinoma and finally to advanced esophageal adenocarcinom. Patients with Barrett's esophagus undergo regular endscopic surveillance for the detection of dysplasia. Dysplatic lesion are, however difficult te detect with standard endoscopy techniques.
A new prototype, Endoscopic TriModal Imaging, incorperates high-resolution white light endoscopy, autofluorescence imaging and narrow band imaging in one systeem. Autofluorescence imagnig excites the esophagus with blue light. The mucosa fluorescence and normal tissue has a different fluorescent spectrum than dysplatic tissue. In uncontrolled studies it was found that autofuorescence may improve the detection of dysplasia. this technique was however also associated with fals-positiv findings. Narrow band imaging is a novel technique that makes use special light filters that improve the imaging of superficial mucosal structures and bloodvessels in the mucosa. Regular mucosal and vascular patterns are associated with non-dysplatic Barrett's and irregular patterns with dysplatic Barrett's. After the detection of suspicious areas with

autofluorescence narrow band imaging can used for the detailed inspection of these area and thus subsequently lower the number of fals positive findings. Patients with a early detected dysplatic/neoplatic lesion(s) can treated curative endoscopically, making an esophagectomy obsolete.

Study objective

Does ETMI improve the dysplasia in Barrett's esophagus?

Study design

A randomised cross-over multi-center study. Patients will undergo two endoscopies, one with ETMI and with the standard technique. Both procuderes will be coonducted by two different endoscopists.

Study burden and risks

An endoscopic procedure is safe. Most complications are related with the sedation during the procedure. Total morbodity of a gastroscopy is between 0.14% and 0.20%. Mortality is 0.07%. The additional risk of a second procedure is very small.

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
Prior diagnosis of Barrett's esophagus
Minimum Barrett's length of C>2M>2 or C<2M>4 according to the Prague C&M classification
Written informed consent

Exclusion criteria

Presence of esophagitis > grade A according to the LA classification of erosive esophagitis
Presence of conditions precluding histological sampling of the esophagus

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-01-2006
Enrollment:	31
Type:	Actual

Ethics review

Not available

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	NL15477.018.06