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.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24455

Source
NTR

Brief title
ETMIC

Health condition

Barrett's esophagus
Autofuorescence imaging
Narrow band imaging

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam
Source(s) of monetary or material Support: Olympus Corp, Tokyo, Japan.

Intervention

Outcome measures

Primary outcome

1. The number of patients and the number of lesions with early neoplasia detected with SVE and ETMI;
2. The number of patients with early neoplasia detected with targeted biopsies only with ETMI and SVE.

Secondary outcome

1. The sensitivity and positive predictive value (PPV) of HRE and AFI;
2. The reduction of false positive findings after NBI;
3. Negative predictive value of the combination of HRE and AFI and the reduction in false negative findings after.

Study description

Background summary

Endoscopic Trimodal Imaging is a new imaging device that incorperates high-resolution white light endoscopy with autofluorescence imaging and narrow band imaging. Our aim of this study is to compare ETMI with standard video endoscopy for the detection of early neoplastic lesions in Barrett's esophagus. In this study high-risk patients reffered for the work-up of high-grade dysplasia or early cancer will included. All prodedures will performed by expert endoscopists in this field in 4 tertiary referal centres for the endoscopic treatment of early Barrett's neoplasia. All patients will undergo two endoscopies (ETMI and SVE) perfromed by two different endoscopists with an interval of 6-12 weeks.

Study objective

ETMI improves the detection of early neoplasia in Barrett's esophagus.

Intervention

In this study we will compare diagnostic endoscopy techniques for the detection of early enoplasia in Barrett's esophagus. These techniques are standard video endoscopy (the current standard) and
Endoscopic Tri-Modal Imaging (ETMI). Patients will undergo two consecutive endoscopies in an interval of 8-12 weeks. One of the two aformentioned techniques will be randomly assigned to the first procedure, the second procedure will subsequently be performed with the other technique by a second endoscopist.
The primary outcome will be the number of lesions and patients with early neoplasia

detected with standard video endoscopy and ETMI.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age > 18 years;
2. Prior diagnosis of BE defined as the presence of columnar lined epithelium in the tubular esophagus with specialised intestinal metaplasia on histological investigation;
3. Prior diagnosis of high-grade dysplasia or early cancer that was endoscopically inconspicuous according to the referring physician. Review of the pathology slides is not required for inclusion;
4. A minimum Barrett's length of C>2M>2 or C<2M>4 according to the Prague C&M classification of the endoscopic appearance of BE;
4. Written informed consent.

Exclusion criteria

1. Presence of active erosive esophagitis > grade A according to the Los Angles classification of erosive esophagitis;
2. Description of an endoscopically visible suspicious lesion in the Barrett's segment in the referring center;
3. Presence of conditions precluding histological sampling of the esophagus (e.g. esophageal

varices, coagulation disorders, anticoagulant therapy);
4. At the first endoscopy: the presence of a type 0-I or type 0-III lesion or a lesion that, according to the discretion of the endoscopist, does not allow a delay in intervention for a period of 6 weeks (interval between the two cross-over endoscopies).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2007
Enrollment:	84
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-03-2007
Application type:	First submission

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
NTR-new	NL921
NTR-old	NTR945
Other	:
ISRCTN	ISRCTN68328077

Study results

Summary results

Curvers WL, Wong Kee Song LM, Wang K, Gostout CJ, Wallace MB, Wolfsen HC, Ragunath R, Fockens P, Bergman JJ. Endoscopic Tri-Modal Imaging (ETMI) for the Detection of Dysplastic Lesions in Barrett's Esophagus; a multi-centre feasibility study. Endosc 2006; 38 (suppl II) A34.