ETMI vs. standard video endoscopy for the detection of early neoplasia in patients with low-grade dysplasia in a Barrett's esophagus: a multi-center randomized cross-over controlled study

No registrations found.

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

Summary

ID

NL-OMON20674

Source
NTR

Brief title
GETMI

Health condition

Barrett's esophagus

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

1. Number of patients with early neoplasia detected with ETMI or SVE;
2. Number of lesions with early neoplasia detected with ETMI and SVE.

Secondary outcome

1. Number of early neoplastic lesions detected with AFI only;
2. Reduction of false positives findings after detailed NBI evaluation.

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 with an intermediate risk profile in a non-expert setting. Barrett's esophagus patients with confirmed low-grade dysplasia by two expert GI pathologist will undergo ETMI and standard video endoscopy by two different endoscopists from non-university hospitals with no specific expertise in the detection of early neoplastic lesions in Barrett's esophagus.

Study objective

ETMI increases the detection rate of early neoplasia in BE patients with 40% or more compared to standard video endoscopy

Intervention

ETMI-gastroscopy and standard video gastroscopy

Contacts

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Eligibility criteria

Inclusion criteria

1. Barrett's esophagus patients with low-grade dyplasia comfirmed by two expert GI pathologists;
2. Written informed consent

Exclusion criteria

1. Presence of active erosive esophagitis grade A according to the Los Angles classification of erosive esophagitis;
2. Presence of conditions precluding histological sampling of the esophagus (e.g. esophageal varices, coagulation disorders, anticoagulant therapy);
3. < 18 years

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):	01-01-2007
Enrollment:	96

Type:	Anticipated

Ethics review

Positive opinion

Date:	08-01-2007
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	NL853
NTR-old	NTR867
Other	: N/A
ISRCTN	ISRCTN91816824

Study results

Summary results

N/A