Endoscopic Tri-Modal Imaging (ETMI) for the detection and classification of early colorectal neoplasia; a multi-center randomized controlled trial

No registrations found.

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

Summary

ID

NL-OMON25050

Source
NTR

Health condition

Colorectal, neoplasia, adenomas, Colonoscopy, Imaging, Detection, classification
Dutch: colon, neoplasie, adenomen, coloscopie, imaging, detectie

Sponsors and support

Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Number of adenomas detected by ETMI versus conventional colonoscopy.

Secondary outcome

1. Number of adenomas detected by HRE versus conventional colonoscopy;
2. Miss rate of HRE as followed by AFI (additional yield of AFI);
3. Accuracy of NBI and AFI in discriminating non-neoplastic from neoplastic lesions (Kudo classification and color)

Study description

Background summary

Colorectal adenomas are being missed by standard colonoscopy in about 22%. New imaging techniques try to reduce miss rates.
Endoscopic Tri-Modal Imaging (ETMI) incorporates (1) autofluorescence imaging and (2) high resolution endoscopy for detection, and (3) narrow band imaging for classification.
This study compares adenoma detection rates of ETMI with standard colonoscopy and evaluates the use of AFI and NBI for correct endoscopic diagnosis.

Study objective

Endoscopic Tri-Modal Imaging increases the detection rate of colorectal adenomas compared to conventional colonoscopy.

Intervention

ETMI tandem colonoscopy: High resolution endoscopy (HRE) followed by autofluorescence imaging (AFI).
Conventional colonoscopy: Standard resolution colonoscopy followed by standard resolution colonoscopy.

Contacts

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Eligibility criteria

Inclusion criteria

Patients (>18 years) undergoing colonoscopic surveillance because of:
a. history of adenomatous polyps.
b. history of CRC.
c. Hereditary Non-Polyposis Colorectal Cancer
d. family history of CRC/adenomas

Exclusion criteria

1. Poor bowel preparation;
2. Familial Adenomatous Polyposis, attenuated FAP, MYH associated polyposis or hyperplastic polyposis;
3. History of inflammatory bowel disease;
4. Presence of conditions precluding histological sampling of the colon (e.g. coagulation disorders, anticoagulant therapy).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-07-2007
Enrollment:	234
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-08-2007
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	NL1010
NTR-old	NTR1039
Other	:
ISRCTN	ISRCTN64206478

Study results