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

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

Summary

ID

NL-OMON30272

Source
ToetsingOnline

Brief title
ETMI-colon

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
colon, polyps

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Olympus,ZonMw (doelmatigheidsonderzoek ronde 2007)

Intervention

Keyword: adenomas, autofluorescence, colorectal neoplasia, narrow band imaging

Outcome measures

Primary outcome

1) Number of patients with adenomatous polyps/neoplasia detected with

Endoscopic Tri-Modality Imaging (ETMI) or Standaard Video Endoscopy (SVE).

2) Number of adenomatous polyps/neoplastic lesions detected with ETMI and SVE

Secondary outcome

1) Number of early neoplastic lesions detected with Auto Fluorescence Imaging

(AFI) only.

2) Reduction of false positives findings after detailed NBI evaluation

(differentiating between hyperplastic and adenomatous polyps).

3) Patients* health condition.

Study description

Background summary

Colorectal carcinoma is one of the commonest cancers in the Netherlands. Its precursor, the adenoma, can be detected and removed during colonoscopy and the patient is cured by complete resection of such lesions. However, it is estimated that 15-27% of small adenomas may be missed during routine colonoscopy. Furthermore, during colonoscopy there is a need for immediate differentiation between neoplastic and nonneoplastic lesions, since neoplastic lesions should be removed during the same session and other lesions may be left in situ. Recently a new endoscopic technique, autofluorescence imaging (AFI), is developed which may improve the detection of early dysplastic lesions. Narrow band imaging (NBI) is another novel endoscopic imaging technique that might be useful in analysing the pit-patterns of the normal and dysplastic

mucosa. Endoscopic Trimodality Imaging incorporates these techniques (AFI, NBI) and may improve the detection and differentiation of early neoplastic lesions.

Study objective

The aim of this randomized controlled multi-center study is to establish whether ETMI improves the detection early colorectal neoplasia compared to standard video endoscopy in a non-expert setting and is effective in differentiating neoplastic from non-neoplastic lesions.

Study design

It is a randomized controlled multi-center study, at six hospitals in the Netherlands.
Patients who are coming for surveillance will be undergo either Endoscopic Tri-Modality Imaging (ETMI) or standard endoscopy for the detection of gastrointestinal neoplasie.
Patients undergoing colonoscopy because of a history of adenomatous polyps, a history of adenocarcinoma of the colon for which partial colectomy was performed, hereditary non-polyposis colorectal cancer or a family history of colorectal cancer at the six participating non-university hospitals will be randomized to undergo either ETMI or standard endoscopy for the endoscopic detection of gastrointestinal neoplasia.
The calculated sample size is 234 patients (117 per group).

Study burden and risks

Increasing the procedural time does not increase the risk of complications. The risk of a diagnostic colonoscopy is minimal (< 1*).

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
- Written informed consent
- History of adenomatous polyps
- History of adenocarcinoma of the colon for which a partial colectomy was performed.
- Hereditary non-polyposis colorectal cancer
- A family history of colorectal cancer according to the revised Bethesda criteria

Exclusion criteria

- Poor bowel preparation
- familial adenomatous polyposis
- history of inflammatory bowel disease
- presence of conditions precluding histological sampling of the colon

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):	01-07-2007
Enrollment:	234
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL15099.018.06