

# Endoscopic Tri-Modal Imaging (ETMI) for the detection and classification of early colorectal neoplasia: a multicentre randomised controlled trial

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<b>Registration date</b> 05/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/10/2015	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A colonoscopy is an examination where a long flexible tube (endoscope) with a light and camera on the end is inserted through your back passage. This enables the doctor or nurse to get a clear view of the bowel lining to look for polyps. These polyps are potentially dangerous because a small number of them become malignant after several years. This is why it is important that the endoscopist finds these polyps and removes them. We know from previous research that a number of polyps are being missed during a colonoscopy. There are different reasons for a polyp to be missed; they can be very small or hidden behind a fold, for example. Normally, a colonoscopy is performed with standard white light. Several new techniques have been developed to improve the quality of colonoscopy. These new techniques have made it possible to better visualize the colon, which could lead to fewer polyps being missed. One of these techniques is called autofluorescence imaging (AFI), another new technique is called narrow band imaging (NBI). During AFI, the colon is being inspected with fluorescing light, while during NBI the colon is being inspected with a particular wavelength of light (mostly blue). Both of these techniques can be incorporated into a normal endoscope. This means that an endoscopist can change between any of the techniques by pressing a button on the endoscope. The aim of this study is to compare the two new techniques (AFI and NBI) with the standard technique, which is normal white light.

### Who can participate?

Patients aged over 18 undergoing colonoscopy because of polyps or colorectal cancer in the past, complaints such as changes in bowel habits or rectal blood loss, or family history of colorectal cancer.

### What does the study involve?

The preparation before the colonoscopy (bowel cleansing) is done as usual. The colonoscopy itself is also similar to a regular colonoscopy. In order to assess whether any of these techniques are better at detecting polyps, we need to know whether any polyps are being missed. This

means that the colon needs to be inspected twice. Participants are randomly allocated into two groups; for one group the colon is inspected twice with standard white light, while the other group will have inspection with white light first and AFI/NBI during the second inspection.

What are the possible benefits and risks of participating?

Colonoscopy is a safe procedure with a very small chance of complications. Because of the double inspection, the colonoscopy is prolonged by about 15 minutes but the risk of complications is not increased.

Where is the study run from?

The study will run in multiple hospitals in the Amsterdam region. These include the Tergooi ziekenhuis Hilversum, Medical Centre Alkmaar, Lucas Andreas Amsterdam, Spaarne Ziekenhuis in Hoofddorp, Flevo Ziekenhuis in Almere and the Onze Lieve Vrouwe Gasthuis in Amsterdam. The lead centre for this study is the Academic Medical Centre in Amsterdam.

When is the study starting and how long is it expected to run for?

July 2007 to December 2008

Who is funding the study?

ZonMw, the Netherlands organisation for health research and development

Who is the main contact?

Dr Evelien Dekker

e.dekker@amc.uva.nl

## Contact information

### Type(s)

Scientific

### Contact name

Dr Evelien Dekker

### Contact details

Academic Medical Centre (AMC)

Department of Gastroenterology and Hepatology

P.O. Box 22660

Amsterdam

Netherlands

1100 DD

+31 (0)20 566 3632

E.Dekker@amc.uva.nl

## Additional identifiers

### Protocol serial number

NTR1039

## Study information

**Scientific Title**

Endoscopic Tri-Modal Imaging (ETMI) for the detection and classification of early colorectal neoplasia: a multicentre randomised controlled trial

**Study objectives**

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

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Received from the local medical ethics committee

**Study design**

Multicentre randomised active-controlled parallel-group trial

**Primary study design**

Interventional

**Study type(s)**

Screening

**Health condition(s) or problem(s) studied**

Colorectal neoplasia

**Interventions**

ETMI tandem colonoscopy: high resolution endoscopy (HRE) followed by autofluorescence imaging (AFI)

Conventional colonoscopy: standard resolution colonoscopy followed by standard resolution colonoscopy

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

Number of adenomas detected by ETMI versus conventional colonoscopy

**Key secondary outcome(s))**

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 narrow band imaging (NBI) and AFI in discriminating non-neoplastic from neoplastic lesions (Kudo classification and colour)

**Completion date**

31/12/2008

**Eligibility****Key inclusion criteria**

Patients (greater than 18 years) undergoing colonoscopic surveillance because of:

1. History of adenomatous polyps
2. History of colorectal cancer (CRC)
3. Hereditary non-polyposis colorectal cancer
4. Family history of CRC/adenomas

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Poor bowel preparation
2. Familial adenomatous polyposis (FAP), attenuated FAP, MutY human homologue (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)

**Date of first enrolment**

10/07/2007

**Date of final enrolment**

31/12/2008

**Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

Academic Medical Centre (AMC)

Amsterdam

Netherlands

1100 DD

**Sponsor information**

**Organisation**

Academic Medical Centre (AMC) (Netherlands)

**ROR**

<https://ror.org/03t4gr691>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

ZonMw

**Alternative Name(s)**

Netherlands Organisation for Health Research and Development

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

Netherlands

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2009		Yes	No
<a href="#">Results article</a>	results	01/06/2011		Yes	No