ISRCTN64206478 https://doi.org/10.1186/ISRCTN64206478

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

Submission date
05/09/2007

Recruitment status
No longer recruiting

Registration date
05/09/2007

Overall study status
Completed

Last Edited
30/10/2015

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 colonscopy. 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

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 measure
Number of adenomas detected by ETMI versus conventional colonoscopy

Secondary outcome measures
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)

Overall study start date
10/07/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
234

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)

Sponsor details
Department of Hepato- and Gastroenterology
P.O. Box 22660
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Sponsor type
Hospital/treatment centre

Website
http://www.amc.nl/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	01/03/2009		Yes	No
Results article	results	01/06/2011		Yes	No