Video autofluorescence imaging for detection of adenomatous POLyps of the colon in intermediate and high-risk PAtieNts

Submission date	Recruitment status No longer recruiting	Prospectively registered		
22/01/2007		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
22/01/2007	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
06/01/2021	Cancer			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

NTR521

Study information

Scientific Title

Video autofluorescence imaging for detection of adenomatous POLyps of the colon in intermediate and high-risk PAtieNts

Acronym

POLPAN study

Study objectives

The aims of the study are:

- 1. To assess the clinical utility and feasibility of autofluorescence imaging (AFI) surveillance colonoscopy in patients with intermediate or high risk for adenomatous polyps
- 2. To determine the additional value of AFI in the detection of polyps in these patients
- 3. To characterise the pit-patterns in the different polyps using narrow band imaging (NBI)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the Medisch Ethische Commissie (Medical Ethical Commitee) Academisch Medisch Centrum (AMC) on the 9th June 2005 (ref: MEC05/097 #05. 17.0799).

Study design

Randomised, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cancer, polyps

Interventions

High resolution white light endoscopy versus autofluorescence endoscopy.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The sensitivity of high resolution white light endoscopy will be compared to that of AFI for detection of polyps and cancer in the colon.

Key secondary outcome(s))

No secondary outcome measures

Completion date

Eligibility

Key inclusion criteria

- 1. Previous adenomatous polyp (polyp-surveillance)
- 2. Previous adenocarcinoma of the colon for which a partial colectomy was performed
- 3. Hereditary non-polyposis colorectal cancer (either genetically proven by a mutation in one of the mismatch repair genes or with a clinical diagnosis according to the Amsterdam II criteria)
- 4. Positive family history for colorectal cancer (CRC): a first-degree family-member fulfills one of the revised Bethesda criteria

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Αll

Total final enrolment

100

Key exclusion criteria

- 1. Familiar adenomatous polyposis
- 2. History of inflammatory bowel disease
- 3. Severe coagulopathy
- 4. Age less than 18 years

Date of first enrolment

01/06/2005

Date of final enrolment

01/12/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Centre (AMC)

Amsterdam Netherlands 1100 DD

Sponsor information

Organisation

Academic Medical Centre (AMC) (The Netherlands)

ROR

https://ror.org/03t4gr691

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (The 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?
Results article	results	01/03/2009	06/01/2021	Yes	No