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

Submission date	Recruitment status	[_] Prospectively registered
22/01/2007	No longer recruiting	[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/06/2005

Completion date
01/12/2006

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

Age group
Adult

Sex
Both

Target number of participants
100

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)

Sponsor details
Department of Gastroenterology
PO Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (The 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	06/01/2021	Yes	No