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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
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

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

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# 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

# 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