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Video AutoFluorescence Imaging (AFI) for dysplasia and cancer in patients with Longstanding Ulcerative Colitis (UC)

Submission date 09/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/01/2006	**Overall study status** Completed	
Last Edited 18/07/2008	**Condition category** Digestive System	

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
NTR498

Study information

Scientific Title

Acronym
AFILUC Study

Study objectives
The aims of the study are:
1. To assess the clinical utility and feasibility of autofluorescence imaging (AFI) in surveillance colonoscopy in patients with longstanding ulcerative colitis (UC)
2. To determine the additional value of AFI in the detection of dysplasia and cancer in these patients
3. To characterise the surface patterns in normal and neoplastic areas in these patients by using narrow band imaging (NBI)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised controlled 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
Ulcerative colitis

Interventions
Patients undergoing surveillance colonoscopy with endoscopic tri-modal imaging (ETMI) received inspections of their colonic segments using:
1. Autofluorescence imaging (AFI)
2. White light endoscopy (WLE)

Each patient received both inspections in a random order.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The value of AFI in patients with UC for detection of dysplasia or cancer.

Secondary outcome measures
No secondary outcome measures

Overall study start date
13/04/2005

Completion date
01/12/2006

Eligibility

Key inclusion criteria
1. Objective diagnosis of UC
2. History of pancolitis
3. Inactive disease determined by a Disease Activity Index

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Known history of colorectal cancer
2. Severe coagulopathy
3. Age less than 18 years

Date of first enrolment
13/04/2005

Date of final enrolment
01/12/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
Department of Gastroenterology
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

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	01/08/2008		Yes	No