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The use of narrow band imaging versus conventional colonoscopy for the detection of dysplasia and cancer in patients with longstanding ulcerative colitis: a randomised cross-over study

Submission date
22/01/2007

Recruitment status
No longer recruiting

Registration date
22/01/2007

Overall study status
Completed

Last Edited
15/01/2021

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL839, NTR853

Study information

Scientific Title
The use of narrow band imaging versus conventional colonoscopy for the detection of dysplasia and cancer in patients with longstanding ulcerative colitis: a randomised cross-over study

Acronym
EVE II study

Study objectives
Aim: to compare Narrow Band Imaging (NBI) and standard White Light Endoscopy (WLE) for the detection of neoplasia during colonoscopic surveillance of patients with longstanding Ulcerative Colitis (UC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Medisch Ethische Commissie (Medical Ethical Commitee) AMC on the 13th December 2006 (ref: MEC06/279 #06.17.1730).

Primary study design
Interventional

Study design
Randomised, controlled, crossover trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ulcerative colitis

Interventions
NBI-Colonoscopy and WLE-colonoscopy.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Number of patients with detected neoplasia.

Key secondary outcome(s)
1. Number of neoplastic lesions
2. Pit pattern classification (Kudo) of neoplastic lesions
3. Vascular pattern description of neoplastic lesions

Completion date
01/07/2008

Eligibility

Key inclusion criteria
1. Objective diagnosis of UC (histologically and/or endoscopically)
2. Extensive UC (proximal to splenic flexure)
3. Disease duration more than eight years
4. Inactive disease (Truelove Witts Index less than two)
5. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Total final enrolment
42

Key exclusion criteria
1. Age less than 18 years
2. Non-correctable coagulopathy

Date of first enrolment
13/12/2006

Date of final enrolment
01/07/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Center (AMC) (The Netherlands)

Alternative Name(s)
Academic Medical Center, Centre Médical Académique, ACADEMISCH MEDISCH CENTRUM AMSTERDAM, Academic Medical Center (Amsterdam), AMC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
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	01/03/2007	15/01/2021	Yes	No