

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

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| Submission date 22/01/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 22/01/2007 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 15/01/2021 | Condition category Digestive System | <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 Committee) AMC on the 13th December 2006 (ref: MEC06/279 #06.17.1730).

Study design

Randomised, controlled, crossover trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Ulcerative colitis

Interventions

NBI-Colonoscopy and WLE-colonoscopy.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Number of patients with detected neoplasia.

Secondary outcome measures

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

Overall study start date

13/12/2006

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

Age group

Adult

Sex

Not Specified

Target number of participants

49

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)

Sponsor details

P.O. Box 22660

Amsterdam

Netherlands

1100 DD

Sponsor type

Hospital/treatment centre

Website

<http://www.amc.uva.nl/#http://www.amc.uva.nl/>

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, AMC

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

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