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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28060

Source
NTR

Brief title
EVE II study

Health condition

longstanding UC

Sponsors and support

Primary sponsor: Academic Medical Centre Amsterdam
Source(s) of monetary or material Support: Academic Medical Centre Amsterdam

Intervention

Outcome measures

Primary outcome

Number of patients with detected neoplasia.

Secondary outcome

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

Study description

Background summary

Patients with longstanding UC will undergo colonoscopic surveillance by both WLE and NBI with a time interval of at least 4 weeks between the procedures. Randomization determines the order of the two techniques. During both procedures targeted biopsies will be taken from suspicious lesions. Only during the second procedure additional random biopsies will be taken according to current clinical guidelines. All detected lesions will be inspected and imaged with NBI and the mucosal morphology and vascular pattern will be classified. The histopathological outcome of the biopsies will be used as the gold standard for diagnosis.

Study objective

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).

Intervention

NBI-Colonoscopy and WLE-colonoscopy.

Contacts

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Eligibility criteria

Inclusion criteria

1. Objective diagnosis of UC (histologically and/or endoscopically);
2. Extensive UC (proximal to splenic flexure);
3. Disease duration > 8 years;
4. Inactive disease (Truelove Witts Index<2);
5. Informed consent.

Exclusion criteria

1. Age < 18 years;
2. Non correctable coagulopathy.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	13-12-2006
Enrollment:	49
Type:	Anticipated

Ethics review

Positive opinion Date:	27-12-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL839
NTR-old	NTR853
Other	: N/A
ISRCTN	ISRCTN56671833

Study results

Summary results
N/A