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

Published: 04-01-2007
Last updated: 09-05-2024

1) to compare NBI and standard White Light Endoscopy (WLE) for the detection of neoplasia during colonoscopic surveillance of patients with longstanding UC2) To determine the accuracy of Kudo*s classification in distinguishing neoplastic from non…

Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON30287

Source
ToetsingOnline

Brief title
EVE II study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
inflammatory bowel disease, ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Olympus Medical Systems, Europe, leverancier van endoscopie materiaal,Olympus Medical Systems;Europe

Intervention

Keyword: colonic neoplasm, comparative study, imaging technique, ulcerative colitis

Outcome measures

Primary outcome

The sensitivity of NBI will be compared to WLE in terms of the number of

patients with detected neoplasia.

Secondary outcome

- In addition, the number of detected neoplastic lesions will be compared

between both techniques.

- Moreover, Kudo*s classification, mucosal morphology and vascular patterns

(imaged by NBI) will be evaluated for their ability to distinguish neoplastic

and non neoplastic lesions.

Study description

Background summary

Patients with longstanding ulcerative colitis (UC) are at increased risk of developing colorectal cancer. To reduce this risk, colonoscopic surveillance is currently recommended in order to detect dysplasia and cancers at an early stage. During surveillance colonoscopy random biopsies should be taken, since neoplastic tissue exists mainly in flat mucosa and is grossly invisible at conventional colonoscopy. Despite this laborious protocol the accuracy of this method is low. The use of dye spraying (chromoendoscopy) has proven to be more accurate for the detection of neoplasia but is labour-intensive and operator dependent. Narrow Band Imaging (NBI) is a novel endoscopic imaging technique with a similar effect as chromoendoscopy but without the use of dyes. This

technique may improve the detection and specification of lesions found during colonoscopy.

Study objective

1) to compare NBI and standard White Light Endoscopy (WLE) for the detection of neoplasia during colonoscopic surveillance of patients with longstanding UC
2) To determine the accuracy of Kudo*s classification in distinguishing neoplastic from non neoplastic lesions using NBI
3) to characterize the mucosal morphology and vascular pattern of neoplastic and non neoplastic mucosa making use of NBI.

Study design

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 burden and risks

The endoscopic procedures are comparable to the standard procedure for regular patient care with the exception of performing the endoscopy twice. The use of NBI does not increase the risk of complications. The accepted risk of a diagnostic colonoscopy is minimal (<0.2%).

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam

Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

objective diagnosis (endoscopically and histologically proven) of ulcerative colitis
extensive colitis (defined as inflammation proximal to the splenic flexure)
disease history longer than 8 years
inactive disease

Exclusion criteria

non correctable coagulopathy
age younger than 18 years
inability to give informed consent

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2007
Enrollment:	49
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL15028.018.06