Chromoendoscopy-guided confocal laser endomicroscopy in the surveillance of patients with Crohn*s disease

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The aims of this study are to assess the prevalence of dysplasia and cancer in Crohn*s disease and to evaluate the accuracy of CCLE during colonoscopy surveillance in Crohn*s disease.

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

Summary

ID

NL-OMON34757

Source
ToetsingOnline

Brief title
Crohn's surveillance with CCLE

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Colon cancer, dysplasia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CCLE, Crohn's disease, surveillance

Outcome measures

Primary outcome

The proportion of patients with neoplasia and the mean number of neoplastic lesions per patient.

Secondary outcome

- The diagnostic accuracy of CCLE for differentiating neoplastic from non-neoplastic mucosa in patients with Crohn*s disease. The proportion of neoplasia found in segments with known Crohn*s disease.

- The diagnostic accuracy of CCLE to differentiate DALMs from ALMs.

- The inter- and intraobserver variability assessing confocal images with and without matching endoscopic images.

Study description

Background summary

The increased cancer risk in longstanding ulcerative colitis (UC) is well established. In comparison, the risk of colorectal cancer in Crohn*s disease (CD) is not as well studied and remains subject of discussion. Furthermore, risk estimates in CD differ considerably and it remains unclear whether dysplasia or cancer arises only in segments with known CD.
In addition, once suspicious lesions are detected endoscopically in inflammatory bowel disease, it is difficult to differentiate lesions from DALMs (requiring proctocolectomy), and from sporadic ALMs (requiring endoscopical resection).
Recent studies have suggested that chromoendoscopy-guided confocal laser endomicroscopy (CCLE) is a more efficient surveillance strategy than standard endoscopy in patients with ulcerative colitis, but this has to our knowledge never been reported in Crohn*s surveillance.

Study objective

The aims of this study are to assess the prevalence of dysplasia and cancer in Crohn*s disease and to evaluate the accuracy of CCLE during colonoscopy surveillance in Crohn*s disease.

Study design

In 4 IBD-referral centres, patients with longstanding Crohn*s colitis in remission undergoing surveillance colonoscopy will be asked to participate in the study. Chromoendoscopy (CE) will be used for detection and differentiation and confocal laser endomicroscopy (CLE) for differentiation of suspicious lesions.
After examination with CCLE, targeted biopsies will be taken of each detected lesion and of mucosa adjacent to each detected lesion. Lastly, 4 quadrant random biopsies each 10cm of the colon will be taken.

Study burden and risks

The endoscopic procedure is comparable to the standard procedure for regular patient care except that procedural time is possibly increased up to a maximum of 15 minutes. Increasing the procedural time does not increase the risk of complication. The risk of complication in a diagnostic colonoscopy is minimal (<1%).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients diagnosed with Crohn*s colitis in remission, with at least 50 cm of the colon involved.
Indication for surveillance colonoscopy (disease duration of more than 8 years or diagnosed with concomitant primary sclerosing cholangitis)
Age >18 years

Exclusion criteria

Contraindications (allergy, pregnancy or breastfeeding, severe cardiopulmonary disease or renal failure) for the use of intravenous fluorescein
Non-correctable coagulopathy that precludes taking biopsies (international normalized ratio >2; or platelet count <90*109)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	23-11-2010
Enrollment:	50
Type:	Actual

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	NL30252.018.09