A new endoscopic technique for the detection of possible malignant mucosal changes in patients with Crohn's disease.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20621

Source
NTR

Brief title
CCLE in CD

Health condition

Crohn's, IBD, dysplasia, chromoendoscopy, endomicroscopy.
Crohn, IBD, dysplasie, chromoendoscopie, endomicroscopie

Sponsors and support

Primary sponsor: Academic Medical Centre, the Netherlands
Source(s) of monetary or material Support: Academic Medical Centre, the Netherlands

Intervention

Outcome measures

Primary outcome

1. Proportion of patients with neoplasia;

2. Mean number of neoplastic lesions per included patient.

Secondary outcome

1. Diagnostic accuracy (defined as sensitivity, specificity and overall accuracy) of CCLE for the differentiation of neoplastic and non-neoplastic mucosa, using final histopathology as reference standard diagnosis;

2. The number of neoplastic lesions found in segments known with Crohn's disease and in segments without Crohn's disease. Crohn's disease is either macroscopically diagnosed or confirmed in histopathology;

3. Diagnostic accuracy of CCLE to differentiate between DALMs and ALMs, using the abovementioned definition as reference standard: DALMs are histologically proven neoplastic lesions with neoplasia in the adjacent 'apparently normal' mucosa, whereas ALMs appear endoscopically as sporadic adenoma and do not demonstrate neoplasia in the adjacent mucosa;

4. The yield of random biopsies, defined by the number of patients with neoplasia detected by random biopsies only (confirmed by histopathology) compared to the total number of patients with neoplasia;

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

Study description

Background summary

Background:

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. 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.

Aims:

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.

Methods:

In 4 IBD-referral centres, patients with longstanding Crohn’s colitis in remission undergoing surveillance colonoscopy will be asked to participate in the study. All patients will undergo colonoscopy using chromoendoscopy (CE) for both 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 objective

What is the prevalence of dysplasia or carcinoma in patients with Crohn's disease that undergo surveillance endoscopy with chromoendoscopy-guided confocal laser endomicroscopy?

Study design

1. Start inclusion: 01-07-2010;

2. End inclusion: 01-07-2011.

Intervention

Each part of the colon (cecum, ascending, transverse, descending, sigmoid colon and rectum) will be sprayed with 0.1% methylene blue solution on withdrawal of the endoscope. In case of detected lesions, intravenous fluorescein (10%) will be administered as contrast and these lesions and their adjacent ‘normal’ mucosa will be inspected by confocal laser endomicroscopy.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients diagnosed with Crohn’s colitis that are in remission;

2. Patients who have Crohn’s disease in at least 50 cm of the colon, based on clinical symptoms, endoscopy and histopathological diagnosis;

3. Indication for surveillance colonoscopy (disease duration of more than 8 years or diagnosed with concomitant PSC);

4. Age >18 years.

Exclusion criteria

1. Contraindications (allergy, pregnancy or breastfeeding, severe cardiopulmonary disease or pre-existent renal disease) for the use of intravenous fluorescein;

2. Known non-correctable coagulopathy that precludes taking biopsies (international normalized ratio >2; or platelet count <90*109). Patients who take anticoagulants will have their international normalized ratio evaluated prior to the colonoscopy;

3. No informed consent.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2010
Enrollment:	101
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-04-2010
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	NL2169

Register	ID
NTR-old	NTR2293
Other	METC AMC : 09/295
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A