Endoscopic screening for dysplasia in patients with longstanding ulcerative colitis: Classical chromo-endoscopy versus NBI, FICE and I-scan

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Assessment of the detection of neoplastic lesions in patients with longstanding ulcerative colitis, using different endoscopic imaging techniques: A: Chromo-endoscopy, methylene blue 0.1% (HDTV Olympus)B: HDTV Olympus colonoscopes and NBIC: Chromo-…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON38174

Source
ToetsingOnline

Brief title
Endoscopic detection of dysplasia in ulcerative colitis

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
dysplasia, ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chromo-endoscopy, Dysplasia, Ulcerative colitis

Outcome measures

Primary outcome

The main study parameter will be the difference between the three different techniques in the detection of neoplastic lesions in patients with longstanding ulcerative colitis.

Secondary outcome

Other end-points are: number of biopsies taken in the different groups, number of detected neoplastic lesions for each technique, number of detected non-neoplastic lesions for each technique, the total number of advanced adenoma defined as adenoma with high grade dysplasia, villous components, intramucosal carcinoma and angio-invasive growth, proportion of patients with low grade adenoma, proportion of patients with high grade adenoma and the duration of total endoscopic procedure time and of endoscopic procedure time during retraction for each technique.

Study description

Background summary

Until today, official international guidelines for endoscopic screening in patients with ulcerative colitis advise to take 4 biopsies every 10 centimeters (with a minimum of 32) and of each suspected visible lesion. These guidelines

are merely based on consensus during expert opinion meetings rather than evidence based. Recent studies have shown that chromo-endoscopy guided biopsies significantly reduced the number of biopsies for each procedure and detected more neoplastic lesions. Chromo-endoscopy is therefore considered the gold standard in this study in which we want to compare it to the performance and efficiency of new endoscopic imaging techniques.
Narrow-Band Imaging (NBI) selectively uses certain wavelengths of the visible light leading to a shift in the excitation spectrum towards blue light. The first studies with NBI showed that the additional value of NBI in the detection of neoplastic lesions is comparable to chromo-endoscopy, but time saving and easier to perform. The Fujinon Intelligent Chromo-Endoscopy (FICE) system uses a similar theoretical principal as NBI but this is achieved via the use of post hoc computer algorithms, applying different filters to the stored endoscopic images and enabling a theoretically endless number of combinations of filters that can be used. The Pentax I-scan system also allows post hoc modification of the images. On the one hand, surface enhancement enables to better highlight mucosal changes. Spectral modification allows to apply different modes in analogy with to FICE system.
These new imaging techniques have a theoretical advantage which is extendedly used for sales purposes but has however so far not been proven in ulcerative colitis patients. We want to test their clinical use in the screening for neoplastic lesions in patients with long standing ulcerative colitis.

Study objective

Assessment of the detection of neoplastic lesions in patients with longstanding ulcerative colitis, using different endoscopic imaging techniques:
A: Chromo-endoscopy, methylene blue 0.1% (HDTV Olympus)
B: HDTV Olympus colonoscopes and NBI
C: Chromo-endoscopy, methylene blue 0.1% (CCD Fujinon)
D: CCD Fujinon colonoscopes and FICE
E: Chromo-endoscopy, methylene blue 0.1% (HD Pentax)
F: HD Pentax colonoscopes and I-scan

Study design

a multi-center international prospective non-blinded randomized trial

Intervention

Screening colonoscopy for ulcerative colitis with different types of colonoscopes and different endoscopic imaging techniques:
Group A: Chromo-endoscopy, methylene blue 0.1% (HDTV Olympus)
Group B: HDTV Olympus colonoscopes and NBI
Group C: Chromo-endoscopy, methylene blue 0.1% (CCD Fujinon)
Group D: CCD Fujinon colonoscopes and FICE

Group E: Chromo-endoscopy, methylene blue 0.1% (HD Pentax)
Group F: HD Pentax colonoscopes and I-scan

Study burden and risks

Risks are associated with colonoscopy procedure, but not with the type of endoscope or use of different endoscopic imaging techniques. No differences in risks between the six study groups is expected or anticipated. Serious risks are very rare in colonoscopy and when occurring, are especially related to interventions during endoscopy (i.e. polypectomy). Risks of diagnostic colonoscopy are significant bleeding in 0.005% and perforation in 0.001% of subjects. However, significant complications of polypectomy are extremely rare. Patients fear will not differ between groups because of blinding of the patient with respect of treatment arm.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

postbus 5800
6202 AZ Maastricht
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

postbus 5800
6202 AZ Maastricht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Signed informed consent form
Patients with longstanding ulcerative colitis: at least 8 years after diagnosis or pancolitis and 10 years after diagnosis of left-sided colitis
Sex: both males and females
Age: above 18 years

Exclusion criteria

Active ulcerative colitis
Personal history of colorectal cancer
Allergy or intolerance to methylene blue
Refusing or incapable to agree with informed consent
Pregnant women

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2011
Enrollment:	164
Type:	Actual

Medical products/devices used

Generic name:	Colonoscope
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-06-2012
Application type:	First submission
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	19-06-2013
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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	NL35347.068.11