Randomised comparison of endoscopic trimodal imaging versus chromoendoscopy as surveillance strategy for neoplasia in ulcerative colitis

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Comparing differentiation and detection of neoplasia in patients with ulcerative colitis undergoing surveillance, by ETMI and CE, in a randomised trial.

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

Summary

ID

NL-OMON40535

Source
ToetsingOnline

Brief title
ETMI vs CE in UC

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,Olympus

Intervention

Keyword: chromoendoscopy, ETMI, surveillance, ulcerative colitis

Outcome measures

Primary outcome

Comparing ETMI and CE for detection of neoplasia in patients with ulcerative colitis

Secondary outcome

- Diagnostic accuracy of ETMI vs. CE for the differentiation of neoplastic and non-neoplastic mucosa, using final histopathology as reference standard diagnosis.

- Determination of endoscopic features that predict the presence of a colitis associated dysplasia (CAD), or a sporadic dysplastic lesion (SDL).

- The yield of random biopsies, defined by the number of patients with neoplasia detected by random biopsies only (confirmed by histopathology).

- Location of neoplasia detected during surveillance colonoscopy

- Mean duration of both endoscopic procedures, ETMI vs. CE

Study description

Background summary

Surveillance colonosocopy in patients with longstanding ulcerative colitis leads to early detection of neoplasia in the colon.Previous research in experienced centers has shown that two surveillance strategies are better that conventional colonoscopy with white light. ETMI, a combination of AFI and NBI, and chromoendoscopy (CE). When neoplasia are detected it remains uncertain whether these are colitis associated or just sporadic, as could happen in every other person.

We expect that both strategies are equally efficient. However, CE is labor-intensive and cost-inefficient, because of the use of Methylene Blue, while ETMI appears to be more time and cost efficient. This research proposal will be the first study that compares ETMI and CE for detection and differentiation of early neoplasia in patients with ulcerative colitis.

Study objective

Comparing differentiation and detection of neoplasia in patients with ulcerative colitis undergoing surveillance, by ETMI and CE, in a randomised trial.

Study design

Randomised contrelled trial: subsequently patients with longstanding ulcerative colitus will be randomised to undergo or ETMI or CE as surveillance colonoscopy.
(1) ETMI: AFI will be used for the detection of neoplastic lesions and AFI and NBI for differentiation of neoplastic and non-neoplastic lesions
(2) CE: CE will be used for both detection as well as differention of the detected lesions.
During colonoscopy targeted biopsies will be taken as well as 4x2 'random' biopsies

Study burden and risks

The endoscopic procedure in this study is comparable with the standard procedure. Besides, the colonoscopy could take a bit longer, with a maximum of 15 minutes, does not bring any extent of burden or risks related to the procedure.The risk on complications in diagnostic colonoscopy is very low (<1%, bleeding/perforation)

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

Assymptomatic patients with ulcerative colitis

Exclusion criteria

- Change in bowel habits in the preceding two months (under maintenance therapy).
- Personal history of (partial) colectomy
- Proven genetic predisposition for colorectal cancer
- Currently known colonic neoplasia
- Non-correctable coagulopathy that precludes taking biopsies
- At introduction active inflammation visible
- Poor bowel preparation
- No informed consent

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-08-2013
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	03-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-08-2013
Application type:	Amendment
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	NL42930.018.12