

ETMI versus Chromoendoscopy in UC

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22789

Source

Nationaal Trial Register

Brief title

FIND-UC

Health condition

Longstanding ulcerative colitis, colonic neoplasia

Langdurige colitis ulcerosa, dikkedarm neoplasieën

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam

Source(s) of monetary or material Support: Olympus

Intervention

Outcome measures

Primary outcome

(1) to compare neoplasia detection rates of autofluorescence imaging (AFI) vs. chromoendoscopy (CE) in patients with ulcerative colitis. (2) to define the mean number of neoplastic lesions per patient.

Secondary outcome

(1) to compare endoscopic trimodal imaging (ETMI) vs. chromoendoscopy (CE) for differentiating neoplastic from non-neoplastic mucosa and (2) to identify diagnostic endoscopic and pathological markers for differentiation between inflammatory dysplasia, that harbour a significant risk on metachronous dysplasia and cancer and might require proctocolectomy, and a sporadic dysplastic lesion that can be safely removed by endoscopic resection.

Study description

Background summary

Randomized trial: consecutive patients with longstanding UC will be randomized to undergo surveillance colonoscopy with either ETMI or CE.

Study objective

CE and AFI are equally effective for the detection of neoplastic lesions in patients undergoing colonoscopic surveillance for UC. Also, the combined use of AFI plus NBI and the use of CE have an equal sensitivity and specificity for the differentiation of non-neoplastic and neoplastic mucosa.

Study design

This multicenter trial will include 210 patients with longstanding ulcerative colitis. We are aiming to include the last patient one year after the start of the study (August 2014). It will take approximately three months time to analyze the data.

Intervention

In this RCT we are comparing ETMI (endoscopic tri modal imaging) with chromoendoscopy in the detection of colonic neoplasia in ulcerative colitis. ETMI is a new endoscopy technique where three types of techniques are incorporated in one device: white light endoscopy, narrow band imaging and autofluorescence imaging. Chromoendoscopy is the technique that nowadays is recommended in IBD (Inflammatory bowel disease) surveillance guidelines. This technique makes use of dye spray to enhance the surface of the colonic mucosa, which is time-consuming. There is data that ETMI is has similar performance as chromoendoscopy, but these two technique have never been compared in a randomised controlled trial.

Contacts

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Eligibility criteria

Inclusion criteria

- History of UC
- Longstanding disease: extensive colitis >8 years (Montreal E3); or left-sided colitis >15 years (Montreal E2)
- Age >18 years

Exclusion criteria

- Change in bowel habits in the preceding two months (under maintenance therapy)
- Personal history of (partial) colectomy
- Clinically unfit for colonoscopy
- Proven genetic predisposition for colorectal cancer
- Currently known colonic neoplasia (e.g. referred patients or patients who refused treatment)
- Known non-correctable coagulopathy that precludes taking biopsies (international normalized ratio

>2; or platelet count <50*10⁹), severe cardiopulmonary disease or renal failure)

- At introduction Mayo-score >1 in at least one of the bowel segments
- Poor bowel preparation (scoring <6 points on the Boston Bowel Preparation Scale) (24)
- No informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-08-2013
Enrollment:	210
Type:	Anticipated

Ethics review

Positive opinion	
Date:	04-07-2013
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	NL3900
NTR-old	NTR4062
Other	NL42930.018.12 : METC 2012_362
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A