Endoscopic Tri-Modal Imaging and Confocal Endomicroscopy for the detection of neoplasia in longstanding ulcerative colitis: a feasibility study.

Published: 24-10-2007
Last updated: 10-05-2024

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

Summary

ID

NL-OMON31990

Source
ToetsingOnline

Brief title
ETMI plus Confocal Endomicroscopy for surveillance of ulcerative colitis.

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
inflammatory bowel disease, ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,Olympus Medical Systems Europe;Hamburg;Germany,Olympus Medical Systems, Hamburg

Intervention

Keyword: autofluorescence imaging, confocal endomicroscopy, narrow band imaging, ulcerative colitis

Outcome measures

Primary outcome

The primary outcomes of this study will be: 1) the neoplasia miss-rate of AFI

(per lesion analysis) and 2) the feasibility of confocal endomicroscopy,

expressed as diagnostic accuracy when compared to final histopathology.

Secondary outcome

Secondary outcomes: 1) the accuracy of AFI plus NBI for the endoscopic

diagnosis of lesions compared to confocal endomicroscopy, and 2) the yield for

neoplasia of real random biopsies compared to optical biopsies by confocal

endomicroscopy.

Study description

Background summary

Patients with longstanding ulcerative colitis (UC) are at increased risk of developing colorectal cancer and therefore undergo regular colonoscopic surveillance. Random biopsies are taken during surveillance, since neoplasia mainly exists in flat mucosa and is grossly invisible at conventional colonoscopy. Random biopsies increase workload and costs for both endoscopists and pathologists. Novel endoscopic imaging techniques like high resolution endoscopy (HRE), autofluorescence imaging (AFI), narrow band imaging (NBI) and confocal endomicroscopy facilitate the detection of neoplasia and improve the discrimination of neoplastic from non-neoplastic mucosa. Hence, the use of these new techniques might eliminate the need for taking random biopsies and might reduce false positive biopsies as well.

Study objective

The aims of this study are: 1) to evaluate the neoplasia miss-rate of AFI in patients with longstanding UC during colonoscopic surveillance; 2) to evaluate the feasibility of miniprobe-based confocal endomicroscopy in these patients; 3) to compare the accuracies of the combined use of AFI plus NBI with confocal endomicroscopy for the endoscopic prediction of histopathology of detected lesions; 4) to compare the yield of random biopsies with the yield of confocal endomicroscopic optical biopsies.

Study design

Patients with longstanding UC will undergo colonoscopic surveillance by AFI. All detected lesions will be inspected by NBI and confocal endomicroscopy for prediction of histopathology. Biopsies from detected lesions will be used as the gold standard diagnosis. After examination by AFI, random biopsies (with HRE) will be taken according to current clinical guidelines. Before taking these random biopsies, confocal endomicroscopy will be performed from the corresponding sampling sites.

Study burden and risks

The endoscopic procedure is comparable to the standard procedure for regular patient care with the exception of performing additional confocal endomicroscopy. The use of AFI and confocal endomicroscopy do not increase the risk of complications. The accepted risk of a diagnostic colonoscopy is minimal (~0%).

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

disease history > 8 years; endoscopic and histopathological evidence of UC; and current inactive disease assessed by the modified Truelove and Witts severity index (of < 2)

Exclusion criteria

allergy to fluorescein; non-correctable coagulopathy; age * 18 years; and inability to give informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	23-10-2007

Enrollment:	20
Type:	Anticipated

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	NL19805.018.07