Observational study; Confocal endomicroscopy in the diagnosis of colorectal neoplasia.

No registrations found.

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

Summary

ID

NL-OMON29543

Source
NTR

Brief title
N/A

Health condition

1. Colorectal cancer (coloncarcinoom);

2. adenomatous polyps (adenomateuze poliepen);

3. chromoendoscopy (chromoendoscopie);

4. confocal endomicroscopy (confocale endomicroscopie).

Sponsors and support

Primary sponsor: Dr. S. Sanduleanu, gastroenterologist
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Source(s) of monetary or material Support: Self-financing research.

Intervention

Outcome measures

Primary outcome

The primary outcome measure will be the number of patients with at least one adenoma after conventional colonoscopy compared with the number of patients with at least one adenoma after pan-chromoendoscopy.

Secondary outcome

Secondary outcome measures assessing the diagnostic accuracy of combined pan-chromoendoscopy and confocal endomicroscopy are: total number of lesions detected; number of adenomas; number of advanced adenomas; number of flat lesions detected.

Study description

Background summary

Rationale:

Colonoscopic surveillace is mandatory in patients at high-risk for colorectal cancer. However some practical issues makes this difficult (e.g. high frequency follow-up, high rate of flat adenomas - a notorious source of interval cancer - , and unnecessary removal of non-neoplastic lesions). Imperative to these data is to improve the accuracy of colonoscopic procedures. The role of confocal endomicroscopy in surveillance of patients at high-risk for CRC has been recently explored. It is presently not clear whether this technique has incremental benefit when added to traditional colonoscopic techniques.
Objective:

Two issues will be addressed:

1. does pan-colonic chromoendoscopy improve the diagnostic yield of colonic polyps (and in particular flat lesions) as compared to conventional colonoscopy?;

2. does pan-colonic chomoendoscopy combined with confocal endomicroscopy result in higher diagnostic accuracy of colonic lesions as compared to conventional histology?;

Study design:

60 patients from either HNPCC families or with familial CRC type X attending for colonoscopic surveillance will be examined twice, first with conventional white-light endoscopy and a second pass with pan-chromoscopy-guided endomicroscopy, in a segmental ‘back-to-back’ fashion. All polyps detected will be removed for histopathological analysis.

The following hypotheses will be tested:

Combined pan-chromoscopic colonoscopy and confocal endomicroscopy result in:

1. Higher adenoma yield, in particular of flat adenomas, mainly due to chromoendoscopy;

2. Improved diagnostic accuracy of neoplastic lesions, in particular:

a. reduction of overdiagnosis;

b. e.g. unnecessary polypectomy of non-neoplastic (low-risk) lesions;

c. reduction of underdiagnosis;

d. e.g. biopsy instead of resection of neoplastic lesions (in particular, the case of admixed serrated adenomas, or in case of sampling errors, etc.) as compared to conventional colonoscopy.

Study objective

To prospectively assess the efficacy of combined pan-chromoendoscopy and confocal colonoscopy for the detection of neoplastic lesions in patients at high-risk for CRC.

Two issues will be addressed:

1. Does pan-colonic chromoendoscopy improve the diagnostic yield of colonic polyps (and in particular flat lesions) as compared to conventional colonoscopy?;

2. Does pan-colonic chomoendoscopy combined with confocal endomicroscopy result in higher diagnostic accuracy of colonic lesions as compared to conventional colonoscopy with biopsies?

Study design

N/A

Intervention

Both techniques (conventional colonoscopy and confocal endomicroscopy) are routinely used in clinical practice at the Department of Gastroenterology of our hospital. In this regard, patients participating in the study will not undergo additional (invasive) examination. As the

duration of the chromoscopy-guided confocal endomicroscopy procedure is somewhat longer than the standard procedure, the patient-burden will possibly increase, mainly due to the ‘back-to-back’ evaluation. The potential advantage is the achievement of higher diagnostic accuracy of preneoplastic lesions in this high-risk population.

During confocal endomicroscopy fluorescein will be administred intravenously, to generate confocal images. This is a safe contrast-agent which has been previously used for the diagnosis of ophtalmologic diseases (e.g. corneal infections). Additionally, fluorescein has been already used in more than 1000 patients undergoing confocal endomicroscopy, without relevant adverse events. Allergic reactions, in particular nausea seldom occur. Also, transient yellow discoloration of urine and skin may occur.

The general risks associated to the colonoscopic procedure are detailed in the endoscopy-folder of the GI Endoscopy Unit of the University Hospital Maastricht.

Contacts

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Eligibility criteria

Inclusion criteria

1. Clinical diagnostic criteria for either HNPCC (Amsterdam II criteria , Bethesda criteria or genetic criteria) or familial colorectal cancer type X – (1) CRC diagnosed age < 50 years;

2. at least 2 first-degree relatives with CRC regardless of age;

3. 1 first-degree and 1 second-degree relative with CRC regardless of age.

Exclusion criteria

1. Age < 18 years, presence of inflammatory bowel disease, or known polyposis syndromes;

2. Patients with incomplete endoscopic procedure due to anatomic or technique-related factors.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2007
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-10-2007
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	NL1061
NTR-old	NTR1094
Other	MEC, academisch ziekenhuis Maastricht : 072090
ISRCTN	Wordt niet aangevraagd/Observational study

Study results

Summary results

1. Confocal laser endomicroscopy: technical status and current indications.
Endoscopy 2006;38(12):1275-83.
Hoffman, A., Goetz, M., Vieth, M., Galle, P.R., Neurath, M.F., Kiesslich, R;
2. Confocal laser endoscopy for diagnosing intraepithelial neoplasias and colorectal cancer in vivo.
Gastroenterology 2004;127(3):706-13.
Kiesslich, R., Burg, J., Vieth, M., Gnaendiger, J., Enders, M., Delaney, P., Polglase, A., McLaren, W., Janell, D., Thomas, S., Nafe, B., Galle, P.R., Neurath, M.F;
3. The role of high-magnification-chromoscopic colonoscopy in hereditary nonpolyposis colorectal cancer screening: a prospective “back-to-back” endoscopic

study.
Am J Gastroenterol 2005; 100:2167-73
Hurlstone, D.P., Karajeh, M., Cross, S.S., McAlindon, M.E., Brown, S., Hunter, M.D., Sanders, D.S.
cancer in vivo.
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Kiesslich, R., Burg, J., Vieth, M., Gnaendiger, J., Enders, M., Delaney, P., Polglase, A., McLaren, W., Janell, D., Thomas, S., Nafe, B., Galle, P.R., Neurath, M.F.