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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29543

Bron
NTR

Verkorte titel
N/A

Aandoening

1. Colorectal cancer (coloncarcinoom);

2. adenomatous polyps (adenomateuze poliepen);

3. chromoendoscopy (chromoendoscopie);

4. confocal endomicroscopy (confocale endomicroscopie).

Ondersteuning

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Overige ondersteuning: Self-financing research.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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?

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2007
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-10-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1061
NTR-old	NTR1094
Ander register	MEC, academisch ziekenhuis Maastricht : 072090
ISRCTN	Wordt niet aangevraagd/Observational study

Resultaten

Samenvatting resultaten

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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