Colonoscopic surveillance using narrow-band imaging in patients with hyperplastic polyposis syndrome (HPS)

Gepubliceerd: 01-09-2008 Laatst bijgewerkt: 18-08-2022

The aims of this study are to assess the additional value of NBI in comparison to white-light endoscopy (WLE) for the detection and classification of HPs, SAs, MPs and adenomas in patients with HPS.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28466

Bron
NTR

Verkorte titel
HYPON

Aandoening

Hyperplastic polyposis syndrome, hyperplastic polyp

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC), Department of Gastroenterology
Overige ondersteuning: Academic Medical Center (AMC), Department of Gastroenterology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The sensitivity of WLE will be compared to that of NBI for the detection of polyps and cancer in the colon. The sensitivity of each technique will be calculated as the number of lesions detected during the first inspection, divided by the total number of lesions detected by both inspections.

Toelichting onderzoek

Achtergrond van het onderzoek

SUMMARY

Background and aim
Hyperplastic polyposis syndrome (HPS) is a condition in which multiple hyperplastic polyps (HPs) are spread throughout the colon. Patients with HPS are at increased risk of developing colorectal cancer (CRC) through a suggested HP-serrated adenoma (SA)-CRC pathway. While complete clearing of all polyps can sometimes prove difficult when multiple lesions exist, regular removal of at least all lesions with a possible risk, e.g. high-risk SAs, MPs and adenomas might adequately prevent the development of CRC. In this respect, endoscopic detection and differentiation of these polyps as well as adenomas is an important undertaking. However, the distinctive endoscopic appearance of SAs has never been described. Novel endoscopic techniques, like narrow-band imaging (NBI) may improve the endoscopic detection and differentiation of polyps in HPS. The aims of this study are to assess the additional value of NBI in comparison to white-light endoscopy (WLE) for the detection and classification of HPs, SAs, MPs and adenomas in patients with HPS.

Methods

Patients with HPS will be evaluated by colonoscopy using a prototype endoscopic imaging system which integrates WLE and NBI in one unit (Spectrum system, Olympus, Tokyo, Japan). All segments of the colon will be inspected twice, using both WLE and the NBI-mode in a randomized order. During the withdrawal phase, any lesion found will be classified according to macroscopic appearance. Size and localization will be recorded. Still images using white light and NBI will be taken and the lesion will be removed. In addition, the pit-pattern according to Kudo [4] will be scored using NBI. During the second withdrawal, after reintroduction to the beginning of the segment, these steps will be repeated using the other modality. The histopathological outcome of the biopsies will be used as the gold standard diagnosis.

Risk

The endoscopic procedure in this study is comparable to the standard procedure for regular patient care except that each segment of the colon will be inspected twice, which may lead to increasing the procedural time with about 15 minutes. Increasing the procedural time does not increase the risk of complications. The risk of a diagnostic colonoscopy is minimal (< 1‰).

Outcome

The sensitivity of WLE will be compared to that of NBI for the detection of polyps and cancer in the colon. The sensitivity of each technique will be calculated as the number of lesions detected during the first inspection, divided by the total number of lesions detected by both inspections. Furthermore, the surface pit pattern of the detected lesions on NBI will be used to obtain the overall accuracy (representing sensitivity and specificity) of this technique, by using the histological diagnosis as the gold standard diagnosis. Moreover, the prevalence and distribution of HPs, SAs, MPs and adenomas in this patient population will be described

Doel van het onderzoek

The aims of this study are to assess the additional value of NBI in comparison to white-light endoscopy (WLE) for the detection and classification of HPs, SAs, MPs and adenomas in patients with HPS.

Onderzoeksopzet

Inclusion: september 2007 - november 2008.

Data analysis: november-december 2008

Onderzoeksproduct en/of interventie

Patients with HPS will be evaluated by colonoscopy using a prototype endoscopic imaging system which integrates WLE and NBI in one unit (Spectrum system, Olympus, Tokyo, Japan). All segments of the colon will be inspected twice, using both WLE and the NBI-mode in a randomized order. During the withdrawal phase, any lesion found will be classified according to macroscopic appearance. Size and localization will be recorded. Still images using white light and NBI will be taken and the lesion will be removed. In addition, the pit-pattern according to Kudo [4] will be scored using NBI. During the second withdrawal, after reintroduction to the beginning of the segment, these steps will be repeated using the other modality. The histopathological outcome of the biopsies will be used as the gold standard diagnosis.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All patients presenting, or under surveillance at the Endoscopy Department of the AMC with:

1. >10 HPs found at colonoscopy, or

2. >5 HPs proximal to the sigmoid colon, or

3. Any number of HPs occurring proximal to sigmoid colon in an individual who has a first-degree relative with HPS.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are

1. History of inflammatory bowel disease,

2. Severe coagulopathy,

3. Age less than 18 years and

4. Insufficient bowel preparation (<90% of colonic mucosa visible).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2007
Aantal proefpersonen:	22
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-09-2008
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	NL1364
NTR-old	NTR1425
Ander register	: MEC 07/220
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A