Colonoscopic surveillance using narrowband imaging in patients with hyperplastic polyposis syndrome (HPS)

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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.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal tract disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON30966

Source ToetsingOnline

Brief title HYPON

Condition

- · Gastrointestinal tract disorders congenital
- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym polyps, tumor

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W

1 - Colonoscopic surveillance using narrow-band imaging in patients with hyperplasti ... 6-05-2025

Intervention

Keyword: adenoma, colon, hyperplastic polyp, serrated

Outcome measures

Primary 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.

Secondary outcome

Moreover, the prevalence and distribution of HPs, SAs, MPs and adenomas in this

patient population will be described.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Study burden and risks

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^*).

Contacts

Public Academisch Medisch Centrum

meibergdreef 9 1105 AZ, Amsterdam Nederland **Scientific** Academisch Medisch Centrum

meibergdreef 9 1105 AZ, Amsterdam

3 - Colonoscopic surveillance using narrow-band imaging in patients with hyperplasti ... 6-05-2025

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

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 firstdegree relative with HPS

Exclusion criteria

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).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

4 - Colonoscopic surveillance using narrow-band imaging in patients with hyperplasti ... 6-05-2025

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	33
Туре:	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 CCMO ID NL19031.018.07