

Incidence of colorectal lesions in first degree relatives of patients with hyperplastic polyposis syndrome (HPS)

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The aims of this study are: 1) To prospectively determine the incidence of HPS/polyps and CRC in first-degree relatives of patients with HPS so as to define whether screening of this group is justified.2) To assess the proportion of individuals that...

Ethical review	-
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON32126

Source

ToetsingOnline

Brief title

PROTECT

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym

growth, tumor

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: colorectal cancer, familial, hyperplastic polyposis syndrome, risk

Outcome measures

Primary outcome

The occurrence, distribution and phenotype (gross morphology, number, size, shape) of polyps and CRC in first-degree relatives of patients with HPS will be assessed. Based on these findings an estimation of the risk of developing polyps/ HPS and CRC in this group can be made so as to define whether screening of this group is justified. In addition, the proportion of individuals that complied with the screening programme will be assessed as well as the proportion of non-compliers. In these two groups, socio-demographic data and potential predictors of compliance behaviour will be compared with the higher aim of designing an effective surveillance programme for these individuals.

Secondary outcome

geen

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. First-degree relatives are also believed to have an increased risk of developing colorectal tumours and are therefore advised to undergo a screening colonoscopy. However, this advice is thus far based on retrospective studies and hence not adequately substantiated.

Study objective

The aims of this study are:

1) To prospectively determine the incidence of HPS/polyps and CRC in first-degree relatives of patients with HPS so as to define whether screening of this group is justified.

2) To assess the proportion of individuals that complied with the screening programme as well as the proportion of non-compliers. In these two groups, socio-demographic data and potential predictors of compliance behaviour will be compared with the higher aim of designing an effective surveillance programme for these individuals

Study design

First-degree relatives of patients with HPS that are currently under surveillance at the Academic Medical Centre will be asked permission to collect their previous colonoscopy data. If they haven't yet undergone a screening colonoscopy, they will be advised to do so, in accordance with current guidelines, at their local hospital or our centre. To investigate the perception and motivation of individuals with regard to endoscopic screening, a combined questionnaire will be given before and after colonoscopy. Furthermore, tissue biopsies and blood samples will be taken and stored for future genetic analysis.

Study burden and risks

The endoscopic procedure in this study is according to the standard procedure for regular patient care. The risk of a diagnostic colonoscopy is minimal (< 1%).

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

First-degree relatives (* 35 years of age or 5 years younger than the lowest incidence age) of patients under surveillance at the Endoscopy Department of the AMC with HPS, defined as:

1) *10 HPs found at colonoscopy, or

2) *5 HPs proximal to the sigmoid colon of which 2 are greater than 10mm in diameter, or

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

Exclusion criteria

Exclusion criteria are 1) individuals who have undergone a colonoscopy in the past three years 2) individuals who have undergone a colectomy 3) severe co-morbidity and 4) age less than 35 years.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 27-10-2008
Enrollment: 55
Type: Actual

Ethics review

Not available

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	NL23190.018.08