Safety of a long-term endoscopic surveillance protocol for serrated polyposis patients

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28738

Source
NTR

Health condition

colorectal cancer, serrated polyposis syndrome

Sponsors and support

Primary sponsor: Academic medical centre, Amsterdam
Source(s) of monetary or material Support: Academic medical centre, Amsterdam

Intervention

Outcome measures

Primary outcome

- Incidence of interval colorectal cancer during protocolled endoscopic surveillance of SPS patients

Secondary outcome

- Incidence and characteristics of polyps found during endoscopic surveillance of SPS patients

- The ratio of annual and biennial surveillance advise

- Incidence of conversion to preventive colorectal surgery

- Incidence of post-colonoscopy complications

Study description

Background summary

Serrated polyposis syndrome (SPS) is characterized by the presence of multiple colorectal serrated polyps and is associated with an increased colorectal cancer (CRC) risk. The prevalance of SPS is estimated to be 1:3000 which makes SPS more common than other polyposis syndromes such as FAP. Due to the risk of malignant polyp transformation, SPS patients undergo endscopic surveillance with removal of polyps or a surgical colonic resection. However, no uniform and adequately substantiated endoscopic management protocol exists regarding polyp removal and surveillance intervals. Earlier research from our research group showed that annual surveillance by experts is safe with regard to interval carcinomas. However annual surveillance could result in systematic overtreatment.

Aim:

To prospectively assess the efficacy, feasibility and safety of a new systemised endoscopic surveillance protocol in which colonoscopic findings will determine the following surveillance interval; one or two years.

Study objective

To prospectively assess the efficacy, feasibility and safety of a renewed systemised endoscopic surveillance protocol in large multicentre HPS cohort.

Study design

5 years

Intervention

Data are collected in prospective manner from patients during routine surveillance endoscopies with removal of all polyps > 3 mm and/or with a adenomatous aspect.

Contacts

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Eligibility criteria

Inclusion criteria

HPS patients defined as:

> 5 HPs/SSA proximal to the sigmoid, of which 2 > 10 mm in diameter, or more than 20 HPs/SSAs distributed throughout the colon.

Exclusion criteria

Carriers of a germline mutation in the MutYH or APC gene and individuals who have undergone a total colonic resection.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2013
Enrollment:	250
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL4476
NTR-old	NTR4609
Other	METC AMC : 10.17.2005

Study results

Summary results

N/A