

Hyperplastic polyposis syndrome: Endoscopic treatment and surveillance.

No registrations found.

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

Summary

ID

NL-OMON27090

Source

Nationaal Trial Register

Brief title

HPSB

Health condition

hyperplastic polyposis CRC serrated adenoma HPSB colorectal carcinoma HPS

Sponsors and support

Primary sponsor: Academic Medical Centre (AMC)

Source(s) of monetary or material Support: Dutch Cancer Society

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

The incidence of complications: The amount of polypectomies and the rate of protocol deviations and conversions to surgical resection will be assessed.

Study description

Background summary

Hyperplastic polyposis syndrome (HPS) is characterized by the presence of multiple colorectal serrated polyps and is associated with an increased colorectal cancer (CRC) risk. The prevalence of HPS is estimated to be 1:3000 which makes HPS more common than other polyposis syndromes such as FAP. Due to the risk of malignant polyp transformation, HPS patients undergo endoscopic 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.

Aim:

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

Study objective

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

Study design

3 years.

Intervention

Data are collected in prospective manner from patients during a routine annual endoscopies with removal of all polyps < 3 mm.

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: | Factorial |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

Recruitment

NL

| | |
|---------------------------|-------------|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-06-2010 |
| Enrollment: | 125 |
| 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 | NL2629 |
| NTR-old | NTR2757 |
| Other | METC AMC : 10.17.2005 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

Study results

Summary results

N/A