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

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

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28738

Bron
NTR

Aandoening

colorectal cancer, serrated polyposis syndrome

Ondersteuning

Primaire sponsor: Academic medical centre, Amsterdam
Overige ondersteuning: Academic medical centre, Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

5 years

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2013
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL4476
NTR-old	NTR4609
Ander register	METC AMC : 10.17.2005

Resultaten

Samenvatting resultaten

N/A