

Incidence of colorectal lesions in first degree relatives of patients with serrated polyposis syndrome.

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To prospectively study the incidence of polyps and CRC in first degree relatives of patients with serrated polyposis syndrome.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27458

Bron

NTR

Verkorte titel

PROTECT

Aandoening

serrated polyposis syndrome, hyperplastic polyposis syndrome, sessile serrated adenoma, colorectal cancer, CRC

Ondersteuning

Primaire sponsor: University of Amsterdam, Academic Medical Center, Department of Gastroenterology

Overige ondersteuning: University of Amsterdam, Academic Medical Center, Department of Gastroenterology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The incidence of CRC, adenoma detection rate (ADR) and presence of multiple (>2) proximal serrated polyps (HPs or SSAs).

Toelichting onderzoek

Achtergrond van het onderzoek

Serrated polyposis syndrome (SPS) is characterized by the presence of multiple colorectal hyperplastic polyps (HPs) and sessile serrated adenomas (SSAs) and is associated with an increased colorectal cancer (CRC) risk. First degree relatives (FDRs) of SPS patients are also believed to have an increased risk for both CRC and SPS, but only scarce retrospective data are available. Prospective evaluation of the magnitude of these risks in FDRs is necessary to determine whether screening colonoscopies are indicated in these persons. The aim of this study is a prospective assessment of the prevalence, distribution and type of neoplasia in FDRs of SPS patients.

We will invite all FDRs > 35 years of age or 5 yrs younger than the index case for a screening colonoscopy. FDRs who had already undergone a colonoscopy in the last 3 years and FDRs with a medical history of CRC will be excluded. All responders undergo a standard white light colonoscopy, either in an academic or local hospital. All polyps are removed or biopsied if very small. Primary outcomes are the incidence of CRC, adenoma detection rate (ADR) and presence of multiple (>2) proximal serrated polyps (HPs or SSAs). In order to assess whether screening colonoscopies are justified in FDRs of SPS patients, we compare the ADR in this cohort with previously reported ADRs in subjects of the same age fulfilling the criteria of familial CRC.

Doel van het onderzoek

To prospectively study the incidence of polyps and CRC in first degree relatives of patients with serrated polyposis syndrome.

Onderzoeksopzet

Inclusion: December 2008 - march 2012.

Data analysis: March 2012.

Onderzoeksproduct en/of interventie

All eligible FDRs are invited to undergo a standard white light screening colonoscopy.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

First degree relatives (>35 years of age or 5 years younger than the lowest incidence age) of SPS patients under surveillance at the endoscopy department.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Individuals who have undergone a colonoscopy in the past three years;
2. Individuals who have undergone a colectomy;
3. Severe co-morbidity;

4. Incomplete colonoscopy;

5. Poor bowel preparation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-12-2008
Aantal proefpersonen:	79
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	19-01-2012
Soort:	Eerste indiening

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	NL3104
NTR-old	NTR3252
Ander register	METC AMC : 08/144
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A