Extra-intestinal manifestations in patients with MYH-associated polyposis (MAP)

Published: 25-09-2007
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The aim of this study is to prospectively assess the occurrence of extra-intestinal manifestations in patients with MAP.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal tract disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON31226

Source
ToetsingOnline

Brief title
Extra-intestinal manifestations in MYH-associated polyposis (MAP)

Condition

- Gastrointestinal tract disorders congenital
- Gastrointestinal neoplasms malignant and unspecified

Synonym
hereditary colorectal cancer, MAP

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: niet van toepassing

Intervention

Keyword: extra-intestinal, FAP, MUTYH, MYH-associated polyposis

Outcome measures

Primary outcome

The occurrence, distribution and phenotype of extra-intestinal manifestations

in patients with MAP will be noted and described. Furthermore, the sensitivity

and specificity will be calculated for these lesions in MAP patients.

Secondary outcome

none.

Study description

Background summary

MYH-associated polyposis (MAP) is an autosomal recessive variant of FAP, which carries a high risk of colorectal cancer (CRC) development. Besides gene testing and endoscopy, the finding of extra-intestinal manifestations can serve as a diagnostic tool to identify FAP patients with an unknown APC mutation. In MAP, extra-intestinal manifestations have been reported (CHRPE, osteomas, dermal lesions and odontomas). However, these reports have all been retrospective and therefore unreliable. By prospectively assessing the prevalence of these lesions in patients with MAP, the finding of extra-intestinal manifestations could prove to be useful in detecting unknown asymptomatic MAP patients.

Study objective

The aim of this study is to prospectively assess the occurrence of extra-intestinal manifestations in patients with MAP.

Study design

All included MYH patients will be interviewed focussing on past medical history, dental abnormalities, orthodontic history and skin lesions. A physical examination will be performed for detection of dermal lesions. Furthermore, patients will undergo an oral & maxillofacial examination and an OPG of the jaw

will be made. Patients undergoing tooth extraction will serve as a control group. Finally, an ophthalmic examination, for the detection of CHRPE, will be performed. Consecutive patients attending the outpatient clinic Ophthalmology will serve as a control group.

Study burden and risks

In this study each patient will receive an OPG of the jaw. This carries an effective radiation dose of approximately 0.1 mSv which is less than the yearly background level of natural radiation of 2-2.5 mSv in the Netherlands.

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

Patients with a germline bi-allelic MYH mutation

Exclusion criteria

age less than 18 years

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	17
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL19109.018.07