

Flat colorectal cancer precursor lesions: epidemiological aspects and molecular analysis.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28777

Source

NTR

Brief title

N/A

Health condition

colorectal cancer, precursor lesions, adenoma, flat, non-polypoid, high-risk population, family history of colorectal cancer

Sponsors and support

Primary sponsor: Maastricht University Medical Center, department of gastroenterology and hepatology

Source(s) of monetary or material Support: Maastricht University Medical Center, department of gastroenterology and hepatology

Intervention

Outcome measures

Primary outcome

1. Prevalence of flat colorectal lesions in a Dutch population;
2. Clinical characteristics (e.g. location of lesions, percentage of high-grade dysplasia or early cancer);
3. Molecular characteristics (epigenetic: methylation status and genetic) of flat vs. polypoid colorectal lesions;
4. Prevalence of flat advanced colorectal cancers vs. polypoid advanced colorectal cancers: clinical features of these lesions (e.g. tumor stage);
5. Relation between serrated and adenomatous polyps.

Secondary outcome

Prevalence and genotype and phenotype associations of flat colorectal lesions in patients at high-risk for colorectal cancer.

Study description

Background summary

N/A

Study objective

1. Flat adenomas are common findings in patients at average- or at high-risk for CRC;
2. Flat adenomas are characterized by a different molecular profile as compared to polypoid lesions; these molecular features are associated with an increased risk for progression to CRC;
3. Serrated polyps are common findings in a population attending for routine colonoscopy.

Study design

Analysis will be performed after the colonoscopy.

Intervention

1. Clinical data registration;
2. Molecular analysis of polypoid vs. flat colorectal lesions.

Contacts

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Eligibility criteria

Inclusion criteria

Patients referred for routine colonoscopy with or without positive family history for colorectal cancer.

Exclusion criteria

Molecular analysis: patients with inflammatory bowel disease.

Study design

Design

Study type: Observational non invasive

Intervention model:	Factorial
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-02-2008
Enrollment:	2500
Type:	Anticipated

Ethics review

Positive opinion	
Date:	30-06-2009
Application type:	First submission

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	NL1781
NTR-old	NTR1891
Other	Metc - Maastricht University Medical Center : MEC 08-4-074
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A