Flat colonic neoplasms: a population-based study

No registrations found.

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

Summary

ID

NL-OMON23392

Source
NTR

Health condition

Colorectaal carcinoom, Darmpoliepen, Poliepen, Adenomen, Vlak, Non-polypoid, Laterally Spreading Tumors, Serrated lesions

Sponsors and support

Primary sponsor: Maastricht University Medical Center (MUMC+), Department of Gastroenterology and Hepatology
Source(s) of monetary or material Support: Maastricht University Medical Center (MUMC+), Department of Gastroenterology and Hepatology

Intervention

Outcome measures

Primary outcome

1. Prevalence of flat colorectal lesions in a Dutch population, especially the prevalence of Laterally Spreading Tumors;

2. Clinical characteristics (e.g. location of lesions, percentage of high-grade dysplasia or early cancer);

3. Molecular charcteristics (epigenetic: methylation status and genetic) of flat vs. polypoid colorectal lesions;

4. Prevalence of flat advanced colorectal cancers vs. polypoid advanced colorecal cancers: clinical features of these lesions (e.g. tumor stage);

5. Relation between serrated and adenomatous polyps.

Secondary outcome

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

Study description

Background summary

The cross-sectional study, initiated in 2008 at the Department of Gastroenterology of the MUMC+, will be prolonged. The focus will be the histopathological and molecular profile of flat adenomas, serrated adenomas and laterally spreading tumors. A cross-sectional cohort of all colonic neoplasms found during routine colonoscopies in an average population, guarantees maximum efficiency in using the present available data and diminishes the need for new patient cohorts in the future.

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. Laterally spreading tumors have a distinct molecular profile compared to large sessile neoplasms;

4. Laterally spreading tumors of the non-granular subtype exhibit a more distinct molecular profile than their granular counterparts;

5. Serrated LSTs will have a distinct molecular profile from adenomatous LSTs.

Study design

Analysis will be performed after each 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 familiy history for colorectal cancer.

Exclusion criteria

Patients with a history of inflammatory bowel disease, polyposis syndrome and proved mutations (APC, MUTYH, MMR) are excluded from analysis.

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:	25000
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-10-2014
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	NL4415
NTR-old	NTR4844
Other	METC - Maastricht University Medical Center : MEC 14-4-046

Study results

Summary results

- Rondagh EJ, Masclee AA, Bouwens MW et al. Endoscopic red flags for the detection of high-risk serrated polyps: an observational study. Endoscopy 2011; 43: 1052-1058
- Rondagh EJ, Sanduleanu S, le Clercq CM et al. Diverticulosis and colorectal polyps at younger age: a possible link? Eur J Gastroenterol Hepatol 2011; 23: 1050-1055
- Rondagh EJ, Bouwens MW, Riedl RG et al. Endoscopic appearance of proximal colorectal neoplasms and potential implications for colonoscopy in cancer prevention. Gastrointest Endosc 2012; 75: 1218-1225
- Rondagh EJ, Masclee AA, van der Valk ME et al. Nonpolypoid colorectal neoplasms: gender differences in prevalence and malignant potential. Scand J Gastroenterol 2012; 47: 80-88
- Bouwens MW, Riedl RG, Bosman FT et al. Large proximal serrated polyps: natural history and colorectal cancer risk in a retrospective series. J Clin Gastroenterol 2013; 47: 734-735
- Bouwens MW, Winkens B, Rondagh EJ et al. Simple clinical risk score identifies patients with serrated polyps in routine practice. Cancer Prev Res (Phila) 2013; 6: 855-863