MicroRNA profiling of colorectal cancer (CRC) and precancerous lesions (adenoma) of CRC

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON31850

Source
ToetsingOnline

Brief title
MAP-CRC

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
colorectal cancer, colorectal neoplasia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: gastrostart grant;possibly MLDS grant

Intervention

Keyword: adenoma, colorectal carcinoma, Micro-RNA

Outcome measures

Primary outcome

miRNAs that are aberrantly expressed in colorectal carcinoma and precancerous

lesions.

Secondary outcome

not appl

Study description

Background summary

MicroRNAs (miRNAs) are a recently discovered class of small (~ 22 nucleotides) non-protein coding (npc) RNA molecules that negatively regulate gene expression by binding to target messenger RNAs (mRNAs). miRNAs are involved in the control of many fundamental cellular and physiological processes such as cellular proliferation and differentiation, development and regulated cell death. In recent years a compelling amount of evidence has been gathered indicating that miRNAs also play a significant role in cellular transformation and carcinogenesis acting either as oncogenes or tumor suppressors. Rather limited information is available for colorectal carcinoma and its precancerous lesions. Up till now only a handful of miRNAs notably let-7, miR-10a, miR-17-92 cluster, miR-20a, miR-24-1, miR-29b-2, miR-31, miR-96, miR-133b, miR-135b, miR-143, miR-145 and miR-183 have been reported to be aberrantly expressed. However, the precise role these and other miRNAs play in colorectal carcinoma is still unclear.

Study objective

The purpose of this project is to determine and analyze miRNA expression profiles from freshly frozen human colon tissue as well colorectal adenomas and carcinomas to identify specific miRNAs or miRNA clusters whose expression is altered in colorectal lesions. The identification of essential miRNAs and their subsequent functional characterization improves our insight in the process of carcinogenesis of colorectal cancer and may lead to novel therapeutic

approaches.

Study design

Biopsies of tumour or polyp and corresponding normal tissue will be obtained during colonoscopy for routine histology evaluation at the Department of Pathology. For this study, four additional biopsies (2mm) will be taken of the polyp or tumour and biopsies of macroscopically normal colonic mucosa of the same bowel segment (ascending colon, transverse colon, descending colon, sigmoid, rectum) as the lesion will be taken.
The miRNA profiling will be performed using an LNA*modified oligonucleotide array platform that was developed in our laboratory and which is capable of detecting the full complement of human miRNAs as registered in the miRNA repository as well as 150 putative miRNAs. Briefly, total RNA will be isolated from biopsies obtained from normal and tumor tissue and from premaligant lesions. Subsequently the RNA is fluorescently labeled and hybridized with Tm normalized LNA* modified capture probes spotted on glass slides. The hybridization signals will be quantified, analyzed and used to generate miRNA expression profiles. Next, various statistical procedures will be employed to identify the miRNAs that are aberrantly expressed in colorectal carcinoma and precancerous lesions in the colon.

Study burden and risks

There is a risk on minimal rectal blood loss until two days after the colonoscopy. The biopsy itself is not painful. The colonoscopy will be lengthened with approx. 4 minutes. The is no personal benefit for the participating patient.

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

· All patients with colorectal polyps or carcinomas
· Age >= 18 year

Exclusion criteria

· Age< 18
· Inflammatory bowel disease
· No informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	01-08-2008
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	09-06-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL22129.078.08