The Scent of Lynch Syndrome

Published: 03-07-2020
Last updated: 11-04-2025

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

Summary

ID

NL-OMON24153

Source
NTR

Brief title
The Scent of Lynch Syndrome

Health condition

Lynch syndrome, colorectal neoplasia (colorectal cancer and polyps/adenomas)

Sponsors and support

Primary sponsor: Maag Lever Darm Stichting (Dutch Gastroenterology patient association)
Source(s) of monetary or material Support: Maag Lever Darm Stichting (Dutch Gastroenterology patient association)

Intervention

Outcome measures

Primary outcome

The accuracy (in terms of sensitivity, specificity and area under the curve) of an electronic nose by means of faecal VOC analysis in detecting colorectal neoplasia (CRC and its

precursors) in patients with Lynch syndrome.

Secondary outcome

* The accuracy (in terms of sensitivity, specificity and area under the curve) of an electronic nose by means of urinal VOC analysis in detecting colorectal neoplasia (CRC and its precursors) in patients with Lynch syndrome. * The accuracy (in terms of sensitivity, specificity and area under the curve) of an electronic nose by means of faecal VOC analysis in follow-up of colorectal neoplasia in patients with Lynch syndrome. * Analysis of the intestinal microbiome in Lynch syndrome patients * The accuracy (in terms of sensitivity, specificity and area under the curve) of faecal amino acid, microbial and protein composition as markers for detection of colorectal neoplasia in patients with Lynch syndrome

Study description

Background summary

National multicentre prospective trial evaluating the use of faecal/urinal VOCs, faecal microbiota, faecal amino acids and faecal protein profiles as markers for detection of colorectal neoplasia in patients with Lynch syndrome. In addition, we will explore the microbial signature in these patients. Patients will fill in questionnaires and stool and urine samples will be collected. VOCs from patients with CRC and/or adenoma(s) detected at surveillance colonoscopy (performed 2-yearly as part of routine care), will be compared to subjects without CRC and adenomas by using an electronic nose (GC-IMS). Faecal microbial composition, amino acids and protein profiles will be analysed using 16 S rRNA amplicon sequencing or (shotgun) metagenomic analysis, High Performance Liquid Chromatography (HPLC) and LC-MS/MS, respectively.

Study objective

We hypothesize that VOCs hold potential as a non-invasive screening tool for detection of colorectal neoplastic lesions in Lynch syndrome. Faecal composition of microbiota as well as amino acids and proteins might be other potential non-invasive biomarkers for CRC and adenoma. Potentially, timing of endoscopy could be guided by non-invasive biomarkers in future. Lastly, patients with Lynch syndrome may harbour an aberrant or different colonic microbiome, that might contribute to the elevated risk of developing colorectal cancer.

Study design

Patients will be asked to collect stool samples at inclusion and then 6-monthly during a two-year period (5 samples). This will include a sample 1 – 4 weeks prior to colonoscopy and three months after colonoscopy. Some patients will also collect urine samples at the same set times. Additionally, Patients will complete a questionnaire on the day of sample collection. Biannual colonoscopy will be performed as part of the routine surveillance

program.

Intervention

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Contacts

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Eligibility criteria

Inclusion criteria

* proven germline mutation in one of the mismatch-repair genes * planned colonoscopy during study period * ≥ 18 years of age * capable of giving informed consent * speak and understand the Dutch language

Exclusion criteria

* No informed consent * Incomplete endoscopic assessment due to various reasons (e.g. inadequate bowel cleansing, pain), unless obstructive CRC is found * Diagnosis of other gastrointestinal diseases besides Lynch syndrome

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2020
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-07-2020
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	NL8749
Other	METC VUmc : 2020.317

Study results