

The Scent of Lynch Syndrome

Gepubliceerd: 03-07-2020 Laatste bijgewerkt: 11-04-2025

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24153

Bron

NTR

Verkorte titel

The Scent of Lynch Syndrome

Aandoening

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

Ondersteuning

Primaire sponsor: Maag Lever Darm Stichting (Dutch Gastroenterology patient association)

Overige ondersteuning: Maag Lever Darm Stichting (Dutch Gastroenterology patient association)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

-

Contactpersonen

Publiek

Amsterdam UMC locatie VUmc
Elisa van Liere

+31 20 444 07 99

Wetenschappelijk

Amsterdam UMC locatie VUmc
Elisa van Liere

+31 20 444 07 99

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- * 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- * 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

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-07-2020
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	03-07-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8749

Register

Ander register

ID

METC VUmc : 2020.317

Resultaten