Linked Color Imaging versus high-definition white light endoscopy for the detection of polyps in patients with Lynch syndrome.
An international, multicenter, parallel randomized controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26181

Source
NTR

Brief title
LCI LYNCH

Health condition

The missing rate of colorectal polyps

Sponsors and support

Primary sponsor: Department of Gastroenterology and Hepatology, C2 Academic Medical Centre
Source(s) of monetary or material Support: FUJIFILM Europe GmbH

Intervention

Outcome measures

Primary outcome

The aim of the present study is to compare polyp detection rates of LCI with high-definition white light endoscopy (HD-WLE) in patients with Lynch syndrome in a parallel, international, multicenter, randomized controlled colonoscopy trial.

Secondary outcome

Secondary objectives of this study are comparisons of mean number of detected polyps, adenoma detection rate, mean umber of adenomas, mean number of serrated polyps, mean duration of procedures, and sensitivity, specificity and accuracy of optical diagnosis on a per polyp basis.

Study description

Background summary

Rationale: Linked Color Imaging is a push-button endoscopic imaging technique developed to enhance the visibility of the vasculature and architecture of the mucosal surface by narrowing the spectrum of absorbed light. Compared to High-Definition White Light Endoscopy, mucosal surface patterns are better visualized and this could potentially increase the detection of polyps by improving the visibility of colorectal polyps. Patients with Lynch syndrome have accelerated carcinogenesis and even the smallest polyps have malignant potential. Increasing polyp detection rates with new imaging techniques is therefore of importance.

Objective: To compare polyp detection rates of Linked Color Imaging with High-Definition White Light Endoscopy during surveillance colonoscopy in Lynch patients

Study design: international, multicentre, parallel, randomized controlled trial

Study population: Patients diagnosed with Lynch syndrome aged ≥ 18 years old

Intervention: Linked Color Imaging colonoscopy or High-Definition White Light Endoscopy

Main study parameters/endpoints: Polyp detection rate of Linked Color Imaging versus High-Definition White Light Endoscopy

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Each colonoscopy is associated with a small, but not negligible risk of bleeding (~1.5%) or perforation (~0.1%). The use of LCI does not increase the

risk of endoscopy.

Study design

-

Intervention

Linked Color Imaging versus high-definition white light endoscopy

Contacts

Public
Department of Gastroenterology and Hepatology, Academic Medical Centre

B. Houwen
Meibergdreef 9

Amsterdam 1105 AZ
The Netherlands
+31 20 5667865
Scientific
Department of Gastroenterology and Hepatology, Academic Medical Centre

B. Houwen
Meibergdreef 9

Amsterdam 1105 AZ
The Netherlands
+31 20 5667865

Eligibility criteria

Inclusion criteria

-Diagnosis of Lynch-syndrome, with a germline mutation in one of the MMR genes (MLH1, MSH2, MSH6, PMS2)

- Age >18 years

- Surveillance colonoscopy for Lynch syndrome.

Exclusion criteria

-Recent surveillance colonoscopy within 1 year from current exam (e.g. after piecemeal EMR) or patients referred for endoscopic evaluation of known colorectal neoplasia.

-Colonoscopy planned for the evaluation of symptoms like rectal blood loss, recent change in bowel habits, weight loss or anemia.

-Patients with a concurrent diagnosis of (serrated) polyposis syndrome or inflammatory bowel disease.

- Patients who are unwilling or unable to give informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2018
Enrollment:	348
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-11-2017

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50151
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6601
NTR-old	NTR6818
CCMO	NL59002.018.16
OMON	NL-OMON50151

Study results

Summary results
nvt