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.

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Fujifilm Linked Color Imaging versus high-definition white light endoscopy for the detection of polyps in patients with Lynch syndrome.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON50151

Source
ToetsingOnline

Brief title
LCI LYNCH

Condition

- Gastrointestinal neoplasms benign

Synonym
Lynch syndrome, polyps

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Fujifilm,Fujifilm Europe

Intervention

Keyword: Colonoscopy, Lynch syndrome, Polyp detection, RCT

Outcome measures

Primary outcome

The primary outcome of the study is the polyp detection rate of HD-WLE and LCI.

Polyp detection rates are defined as the number of patients with at least 1

polyp detected during the inspection divided by the total number of patients

included in the study.

Secondary outcome

- The difference in mean number of polyps between HD-WLE and LCI

- The difference in adenoma detection rate between HD-WLE and LCI

- The difference in mean number of adenomas between HD-WLE and LCI

- The difference in mean number of serrated polyps between HD-WLE and LCI

- The mean duration of both endoscopic procedures LCI vs. HD-WLE: time for

inspection and time for performing endoscopic resection

- The sensitivity, specificity and accuracy of optical diagnosis on a per polyp

basis

Study description

Background summary

Fujifilm 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.

Study objective

Fujifilm Linked Color Imaging versus high-definition white light endoscopy for the detection of polyps in patients with Lynch syndrome.

Study design

An international, multicenter, parallel randomized controlled trial.

Intervention

Linked Color Imaging (LCI)

Study burden and risks

Each colonoscopy is associated with a small, but not negligible risk of bleeding (~1%) or perforation (~0.1%). The use of LCI does not increase the risk of endoscopy.

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

- Diagnosis of Lynch-syndrome, with a germline mutation in one of the MMR genes (MLH1, MSH2, MSH6, PMS2)
- Surveillance colonoscopy for Lynch syndrome.
- Age >18 years

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:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-01-2018
Enrollment:	134
Type:	Actual

Medical products/devices used

Generic name:	Advanced endoscopic imaging technology
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-04-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-02-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-06-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-06-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-10-2019

Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26181
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL59002.018.16
OMON	NL-OMON26181

Study results

Date completed:	13-03-2020
Actual enrolment:	122

Summary results
Trial is onging in other countries