Back-to-back high-definition white light endoscopy versus single-pass high-definition white light endoscopy and chromoendoscopy in IBD surveillance (HELIOS study)

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Assessment of the detection of neoplastic lesions in patients with longstanding inflammatory bowel disease, using different endoscopic imaging techniques. Colonoscopy will be performed with either A) HDWLE, B) back-to-back HDWLE or C) CE.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON49570

Source
ToetsingOnline

Brief title
HELIOS study

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal neoplasms benign

Synonym
inflammatory bowel diseases

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: back-to-back, chromoendoscopy, IBD, white light

Outcome measures

Primary outcome

The detection rate of neoplasia (i.e. dysplasia and CRC) with the different

endoscopic modalities

Secondary outcome

1. Number of all lesions for each technique.

2. Number of dysplastic lesions for each technique.

3. Characteristics of lesions: Kudo classification, Paris classification,

location, size

4. Number of lesions detected at first and second examination (only in group

back-to-back HDWLE)

5. Duration of total endoscopic procedure time and endoscopic procedure time

during withdrawal for each technique.

6. Number of biopsies taken in the different groups.

Study description

Background summary

Patients with long-standing inflammatory bowel disease (IBD) have an increased risk of developing colorectal cancer (CRC)(1). In IBD, chronic inflammation may lead to the development of mucosal dysplasia that can progress to

colitis-associated CRC. To decrease CRC-related mortality and morbidity, guidelines recommend enrolling patients in an endoscopic surveillance program in order to detect and remove dysplasia before progressing to more advanced lesions.

High-definition endoscopic visualisation techniques have improved the dysplasia detection rate compared to standard-definition white light endoscopy (2). To further enhance the image contrast, dye-based chromoendoscopy (CE) can be used. The current international guidelines recommend as first choice the use of CE, and as an alternative high-definition white light endoscopy (HDWLE) for optimal dysplasia detection, based on data from clinical trials (3, 4). However, data on the superiority of CE over HDWLE are not consistent in literature (5, 6). We hypothesize that the better performance of CE in some clinical trials is the result of the associated longer procedural time of 11 minutes with CE (7), and the fact that every colon segment is examined twice due to the need for spraying every colon segment before re-examination. Indeed, previous studies have shown that a longer procedural time and procedures during which the mucosa is visualized twice (back-to-back) are associated with a higher adenoma detection rates in non-IBD patients (8, 9). Currently, no studies have been published evaluating the dysplastic yield of back-to back HDWLE compared to HDWLE with a single pass or CE in patients with IBD.

In the present study, we aim to compare the yield of dysplasia/CRC between 1) regular HDWLE, 2) HDWLE back-to-back, and 3) CE.

Study objective

Assessment of the detection of neoplastic lesions in patients with longstanding inflammatory bowel disease, using different endoscopic imaging techniques. Colonoscopy will be performed with either A) HDWLE, B) back-to-back HDWLE or C) CE.

Study design

A multi-center, prospective, non-blinded randomized trial. In all participating centers, eligible patients will be randomized between groups A, B or C. The study will be performed at the following centers: Radboudumc Nijmegen, University Medical Center Utrecht, Leiden University Medical Center, and Amsterdamumc location AMC.

Intervention

A) HDWLE, B) back-to-back HDWLE or C) CE.

Study burden and risks

Colonoscopy is a commonly performed procedure with a very low overall serious adverse event (SAE) rate of approximately 2.8 per 1000 colonoscopies. Diagnostic colonoscopy has a bleeding risk of 0.1% and a perforation risk of 0.01% of subjects. These risks are associated with regular surveillance colonoscopies in daily practice and not expected to increase due to our intervention. The bleeding risk of multiple biopsies is considered extremely low (0.008% to 0.03% (10)). The burden related to this study includes the additional burden of a second look in a select group of patients. There are also some substantial benefits. Although a single pass with HDWLE is currently part of standard practice when CE is not applied, it has been shown that a single examination has a miss-rate of polyps of 16.8% to 28% (11-13). Back-to-back colonoscopy may result in the detection (and subsequent removal) of more neoplastic lesions, which has been shown to be inversely correlated with the development of interval carcinomas(14).

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

- Signed informed consent
- Patients with inflammatory bowel disease, an estimated involvement of at least 30% of the colonic surface and a disease duration of at least 8 years (or any disease duration in case of concomitant primary sclerosing cholangitis).
- Previous assessable surveillance endoscopy > 1 year
- Age > 18 years

Exclusion criteria

- Active colitis > 20 cm and/or inflammation resulting in an insufficient surveillance procedure according to the endoscopist.
- Allergy or intolerance to methylene blue
- Insufficient bowel cleansing (BBPS <6)
- Refusing or incapable to agree with informed consent
* Pregnant women
* > 50 % of the colon surgically removed

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:	Recruiting
Start date (anticipated):	13-03-2020
Enrollment:	560

Type:	Actual

Ethics review

Approved WMO Date:	20-02-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-06-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-12-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-03-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
ClinicalTrials.gov	NCT04291976

Register	ID
CCMO	NL72006.091.19