

Comparing autofluorescence endoscopy and white light video endoscopy for surveillance of patients with familial colorectal cancer.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23207

Source

NTR

Brief title

CAESAR study

Health condition

Lynch syndrome, familial colorectal cancer
colonoscopic surveillance

Dutch:

Lynch syndroom
familiaire colorectaal carcinoom
colonoscopische surveillance

Sponsors and support

Primary sponsor: None

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The difference between WLE and AFE for detection of adenomatous lesion or CRC during colonoscopy in patient with HNPCC or familial CRC.

Secondary outcome

1. Histological difference of the lesions detected only by WLE or only by AFE;
2. Duration of the procedure for WLE and AFE.

Study description

Background summary

Objective:

To compare the sensitivity of autofluorescence endoscopy (AFE) and white light video endoscopy (WLE) for the detection of colorectal adenomas in high-risk patients belonging to Lynch syndrome (LS) or familial colorectal cancer (CRC) families.

Design:

Prospective single centre study.

Setting:

Tertiary referral centre.

Population:

Asymptomatic patients originating from Lynch syndrome or familial colorectal cancer families.

Intervention:

Patients were examined with either WLE followed by AFE or AFE followed by WLE. Back-to-back colonoscopy was performed by two blinded endoscopists. All lesions were removed during the second endoscopic procedure. Lesions missed during the second procedure were identified and removed on 3rd pass. The sensitivity calculations for colorectal adenomas were based on histology results.

Outcome measure:

The difference in sensitivity between WLE and AFE for the detection of adenomas in patients with LS or familial CRC.

Analysis:

McNemar's test, the Mann-Whitney U test, the Fisher exact test, the t-test and multivariable proportional odds logistic regression analysis.

Study objective

Autofluorescence endoscopy (AFE) has a higher sensitivity for the detection of colorectal adenomas in comparison with white light video endoscopy (WLE).

Study design

Interim analysis after inclusion of fifty participants.

Intervention

Colonoscopic surveillance with both WLE and AFE in high risk patients (Lynch syndrome or familial colorectal cancer). In case of the detection of colorectal lesions (adenoma, colorectal cancer or hyperplasia) these lesions were removed by polypectomy. AFE was compared to WLE (active control) with respect to the diagnostic yield (detection of colorectal lesions).

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18 years or older;
2. Patients with Lynch syndrome, defined according to the Amsterdam 2 criteria;
3. Patients with familial colorectal cancer (IKR Guidelines; www.oncoline.nl):
 - A. One first degree family member with colorectal carcinoma diagnosed at a relative young age or in two second degree family members and;
 - B. Lynch syndrome or Familial adenomatous polyposis is excluded.

Exclusion criteria

1. Under 18 years of age;
2. Patients with (attenuated) FAP;
3. Coagulopathy (prothrombin time < 50% of control; partial thromboplastin time > 50 seconds) or anticoagulantia that can not be discontinued;
4. Patients with inflammatory bowel disease;
5. Patients with Peutz-Jeghers syndrome or juvenile polyposis;
6. Patients unable or not willing to give

informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	11-11-2005
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion	
Date:	17-06-2009
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 NL1756

NTR-old NTR1865

Other Medical ethical committee Erasmus MC University Medical Center : MEC-2005-199

ISRCTN ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A