Diagnosis of small colorectal lesions in a non-academic setting.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26990

Source
Nationaal Trial Register

Brief title
DISCOUNT

Health condition

differentiation
colorectal lesions
white-light
narrow-band imaging
optical diagnosis

Sponsors and support

Primary sponsor: Academic Medical Centre
Source(s) of monetary or material Support: Academic Medical Centre

Intervention

Outcome measures

Primary outcome

The accuracy of the optical diagnosis, combining white-light and NBI (using Kudo pit-pattern

and VPI), in lesions smaller than 10mm that are differentiated with high confidence.

Secondary outcome

1. The percentage of all lesions that is differentiated with high confidence by the endoscopist and the percentage of lesions differentiated with high confidence by white-light only;

2. The difference in accuracy of optical diagnosis of lesions differentiated with high confidence according to size (0-5mm vs. 6-9mm) and the difference in prevalence of (advanced) adenomas in these groups;

3. The difference in accuracy of VPI and Kudo pit pattern for differentiation of small colonic lesions;

4. The percentage of patients who have their surveillance intervals based on optical diagnosis alone, according to Dutch guidelines.

Study description

Background summary

Background:

Several endoscopic imaging techniques have recently been developed in order to improve differentiation of premalignant adenomas from innocent, non-neoplastic polyps. Accurate in-vivo optical diagnosis of polyps less than 10mm in size can be an acceptable strategy to assess polyp histopathology and future surveillance intervals. Furthermore, dispensing without formal histopathology for most small polyps could improve the efficiency of the procedure and lead to substantial savings in time and costs. This surveillance strategy based on optical diagnosis appears suitable for incorporation in future guidelines but has never been assessed in a non-expert setting.

Aims:

This study proposal aims to assess the accuracy of optical diagnosis with white light and narrow-band imaging (NBI) in colonic lesions smaller than 10 mm in a non-expert setting. Furthermore, the difference in accuracy of Kudo pit-pattern and VPI during NBI for differentiation will be assessed.

Methods:

Each detected lesion will be inspected with high definition white light endoscopy and NBI (Kudo pit pattern and VPI) for differentiation and the endoscopist will be asked to predict histopathology. Subsequently, the endoscopist will state on the basis of optical diagnosis alone whether he has high confidence in differentiating the lesion (e.g. whether he would leave it in situ or resect and discard the lesion) or whether he has low confidence in differentiating the lesion (e.g. resect and send the polyp for histopathology).
Regardless of the confidence of the endoscopist, all lesions included in the analysis will be biopsied or resected at the end of the optical diagnosis and send for histopathology.

Study objective

The current study evaluates whether accurate optical diagnosis of small colorectal polyps (<10mm) in vivo in a non-expert setting can be achieved, resulting in the omission of formal histopathology, which could make colonoscopy more efficient and cost effective.

Study design

N/A

Intervention

All participating endoscopists differentiate colorectal lesions with white-light and NBI and will indicate whether they have high confidence or low confidence in the differentiation. Subsequently, the endoscopists will decide on the management of the lesion; whether they will resect and discard it (high confidence, no formal histopathology), resect and send it for histopathology (low confidence, if they cannot decide on the type of polyp or are concerned about malignancy) or leave it in situ (high confidence). Furthermore, a recommendation for surveillance interval is recorded.

For study purposes, all lesions included in the analysis will be biopsied or resected at the end of the optical diagnosis and send for histopathology.

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Eligibility criteria

Inclusion criteria

1. Age > 18 years;

2. Patients who are advised to undergo colonoscopic surveillance because of:

A. A history of adenomatous polyps or colorectal cancer (CRC);

B. Symptoms (e.g. change in bowel habits);

C. Family history of CRC.

Exclusion criteria

1. Poor bowel preparation (less than 90% visualization);

2. Polyposis syndromes;

3. Patients with obvious cancer during colonoscopy;

4. Patients with lesions >10mm only;

5. History of inflammatory bowel disease;

6. Presence of conditions precluding histological sampling of the colon (e.g. coagulation disorders, anticoagulant therapy).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-09-2010
Enrollment:	277
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL2667
NTR-old	NTR2795

Register	ID
Other	Correspondence number METC AMC : WII-019# 11.17.0276
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A