

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

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The current study evaluates whether accurate optical diagnosis of small colorectal polyps (

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26990

Bron

Nationaal Trial Register

Verkorte titel

DISCOUNT

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Centre

Overige ondersteuning: Academic Medical Centre

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm

Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	07-09-2010
Aantal proefpersonen:	277
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2667
NTR-old	NTR2795
Ander register	Correspondence number METC AMC : WII-019# 11.17.0276
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A