

Diagnosing small lesions in the colon using the WavSTAT device.

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25180

Bron

NTR

Verkorte titel

WavSTAT

Aandoening

differentiation, colonoscopy, white light, WavSTAT, optical diagnosis

Ondersteuning

Primaire sponsor: Academic Medical Centre, Amsterdam, the Netherlands

Overige ondersteuning: Probes in this trial are provided by Spectrascience Inc., San Diego, CA, USA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. The overall accuracy of the WavSTAT represented by the sensitivity and specificity using final histopathology as golden standard;

2. The accuracy of the WavSTAT of lesions that are differentiated with white light endoscopy

with low confidence, represented by the sensitivity and specificity using final histopathology as golden standard.

Toelichting onderzoek

Achtergrond van het onderzoek

WavSTAT (Spectrascience, Inc., San Diego, CA, USA) is an optical biopsy system that can aide endoscopists in differentiation of colorectal lesions. Accurate differentiation of small colorectal lesions can result in removal of these lesions without formal histopathology making colonoscopy more efficient and cost-effective.

The laser light of the WavSTAT is absorbed by colonic tissue resulting in an autofluorescent return signal, which is subsequently analysed. Within seconds a 'non-adenomatous' or 'adenomatous' result is displayed on a screen. The WavSTAT can be particularly useful as an add-on technique for differentiation of colorectal lesions that the endoscopist differentiates with low confidence using white light (WL).

The aim of the current study is to assess the sensitivity, specificity and accuracy of an algorithm combining WL and WavSTAT. In this algorithm, overall accuracy is defined by WL in high confidence lesions and by WavSTAT in low confidence lesions.

Doel van het onderzoek

The current study evaluates whether accurate optical diagnosis of small colorectal polyps (<10mm) can be achieved using both the endoscopic image as well as an optical device called the WavSTAT. Accurate optical diagnose could result in the omission of formal histopathology, which could make colonoscopy more efficient and cost effective.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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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;
 - 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 (scoring ≤ 4 points on the Boston Bowel Preparation Scale 8);

2. Polyposis syndromes;
3. History of inflammatory bowel disease;
4. Presence of conditions precluding histological sampling of the colon (e.g. coagulation disorders, anticoagulant therapy).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	24-03-2011
Aantal proefpersonen:	205
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	02-01-2012
Soort:	Eerste indiening

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	NL3087
NTR-old	NTR3235
Ander register	METC AMC : MEC 10/299
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A