# Diagnosing small lesions in the colon using the WavSTAT device.

No registrations found.

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

# **Summary**

# ID

NL-OMON25180

Source NTR

**Brief title** WavSTAT

#### Health condition

differentiation, colonoscopy, white light, WavSTAT, optical diagnosis

# **Sponsors and support**

**Primary sponsor:** Academic Medical Centre, Amsterdam, the Netherlands **Source(s) of monetary or material Support:** Probes in this trial are provided by Spectrascience Inc., San Diego, CA, USA

## Intervention

## **Outcome measures**

#### **Primary outcome**

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

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

#### Secondary outcome

1. The percentage of lesions that is differentiated with white light endoscopy with high confidence;

2. The difference between trainees and expert endoscopists regarding the percentage of lesions that is differentiated with high confidence with white light endoscopy;

3. The accuracy for predicting histopathology in lesions that are differentiated with high confidence with white light endoscopy;

4. The difference in accuracy between trainees and expert endoscopists for predicting histopathology in lesions that are differentiated with high confidence with white light endoscopy.

# **Study description**

#### **Background summary**

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.

#### **Study objective**

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.

#### Study design

N/A

#### Intervention

N/A

# Contacts

#### Public

Academic Medical Center (AMC) <br> Department of Gastroenterology and Hepatology <br> P.O. Box 22660 **Evelien Dekker** Meibergdreef 9 Amsterdam 1105 AZ The Netherlands +31 (0)20 5664702 Scientific Academic Medical Center (AMC) <br> Department of Gastroenterology and Hepatology <br> P.O. Box 22660 **Evelien Dekker** Meibergdreef 9 Amsterdam 1105 AZ The Netherlands +31 (0)20 5664702

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

C. Family history of CRC.

# **Exclusion criteria**

- 1. Poor bowel preparation (scoring  $\leq$  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).

# Study design

## Design

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

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	24-03-2011
Enrollment:	205
Туре:	Actual

# **Ethics review**

Positive opinion Date: Application type:

02-01-2012 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	NL3087
NTR-old	NTR3235
Other	METC AMC : MEC 10/299
ISRCTN	ISRCTN wordt niet meer aangevraagd.

# **Study results**

Summary results N/A