Implementation of optical diagnosis for diminutive polyps amongst accredited endoscopists for the Dutch bowel cancer screening program: training and longterm quality assurance.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

## Summary

## ID

NL-OMON24207

Source NTR

Brief title DISCOUNT II

#### **Health condition**

Randomized control trial Colonic Polyps/diagnosis\* Colorectal Neoplasms/diagnosis\* Colonic Polyps/pathology\* Colonoscopy\*/economics Health care costs Sensitivity and Specificity Hospitals, community Early Detection of Cancer

Eventueel:
Male
Female
Adult

1 - Implementation of optical diagnosis for diminutive polyps amongst accredited end ... 5-05-2025

## **Sponsors and support**

Primary sponsor: AMC Dutch Maag-Lever-Darm Stichting Source(s) of monetary or material Support: Dutch Digestive Funds (MLDS)

### Intervention

### **Outcome measures**

#### **Primary outcome**

Primary aims

1) Number of training rounds needed to reach clinically acceptable prediction of histology (accuracy > 90%) for colorectal lesions

2) To assess whether qualified endoscopists are able to maintain this performance over a year, and if feedback is of additional value

#### Secondary outcome

Secondary aims:

1) number of endoscopists reaching NPV > 90% for predicting neoplastic histology in continuation phase

- 2) number of correctly advised surveillance intervals
- 3) number of correctly predicted diminutive (1-5mm) lesions
- 4) number of surveillance intervals predicted on endoscopic diagnosis
- 5) number of correctly diagnosed small (6-9mm) lesions
- 6) budget impact analysis

# **Study description**

#### **Study objective**

2 - Implementation of optical diagnosis for diminutive polyps amongst accredited end ... 5-05-2025

1) Whether endoscopists are able to learn optical diagnosis of colonic polyps using NBI by a validated training and feedback program

2) Whether these endoscopists are able to reach the threshold provided by the PIVI guidelines for predicting the diagnosis of diminutive lesions

3) Whether regular measurement and feedback of optical diagnosis will be needed to assure the quality of this optical diagnosis strategy.

### Study design

- 3-monthly feedback with up-to-date accuracy, negative predictive value, sensitivity and specificity on optical diagnosis of diminutive (1-5mm) and small (6-9mm) polyps.

- Overview of NICE/WASP/KUDO optical diagnosis principles

#### Intervention

Validated training, qualification and 3-monthly feedback

# 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**

Patients: all those with polyps who receive a coloscopy in the context of the Dutch bowel cancer screening program

Endoscopists: all those who are accredited to perform colonoscopies for the nationwide Dutch bowel colorectal cancer screening program

## **Exclusion criteria**

Patients with inflammatory bowel disease. Patients who had a CRC before.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

### Recruitment

. . .

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2015
Enrollment:	30
Туре:	Anticipated

4 - Implementation of optical diagnosis for diminutive polyps amongst accredited end ... 5-05-2025

# **Ethics review**

Positive opinion Date: Application type:

05-06-2014 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	NL4517
NTR-old	NTR4635
Other	METC AMC: W14_099 : MLDS: FP-13

## **Study results**