

# Endoscopic surveillance using narrow-band imaging in patients with hyperplastic polyposis syndrome (HPS): A multi-centre cohort study.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON23826

### Source

NTR

### Brief title

ECLIPSE

### Health condition

Hyperplastic  
Polyposis  
Syndrome  
Narrow Band Imaging

## Sponsors and support

**Primary sponsor:** Academic Medical Center, University of Amsterdam

**Source(s) of monetary or material Support:** fund = initiator = sponsor

## Intervention

## Outcome measures

### Primary outcome

Polyp miss-rates of NBI vs. HRE.

### Secondary outcome

The diagnostic accuracy of NBI-VPI vs. HRE-VPI for the differentiation of polyps.

## Study description

### Background summary

N/A

### Study objective

Hyperplastic polyposis syndrome (HPS) is characterized by the presence of multiple colorectal serrated polyps and co-existent conventional adenomas and is associated with an increased colorectal cancer (CRC) risk 1-9. Considering the presumed increased risk of malignant progression of polyps in HPS, detection and removal of polyps seems necessary to prevent CRC development in these patients. However, serrated polyps, which are the overall majority in HPS, are generally small in size, flat in shape and unremarkable in colour. These features are associated with polyp miss-rates of up to 26% using standard colonoscopy. Narrow-band imaging (NBI) may improve the detection and differentiation of these polyps.

### Study design

1. Inclusion: october 2010- end 2011;
2. Data analysis: december 2011.

### Intervention

All patients will undergo tandem colonoscopy with HRE and NBI, in randomized order with removal of all detected polyps  $\geq 3$  mm after characterization for Kudo pit pattern and vascular pattern intensity (VPI).

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

All HPS patients, defined as having:

1.  $\geq 5$  HPs/SSAs proximal to the sigmoid colon of which 2 are greater than 10mm in diameter or;
2.  $\geq 20$  HPs/SSAs spread throughout the colon.

### **Exclusion criteria**

1. Patients carrying a germline mutation in the MutYH (biallelic) or APC gene and individuals who have undergone a total colonic resection;
2. History of inflammatory bowel disease;
3. Severe coagulopathy;
4. Age less than 18 years and;
5. Insufficient bowel preparation (<90% of colonic mucosa visible).

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2010
Enrollment:	52
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	03-09-2010
Application type:	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	NL2390
NTR-old	NTR2497
Other	METC AMC : 10/160
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A