

# Dye chromoENDOscoPy versus virtual chromoendoscopy for assessment of the ileo-anal pouch in patients with familial adenomatous POLyposis: a randomized controlled trial

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The primary outcome of this study is the detection of clinical relevant adenomas ( $\geq 5\text{mm}$ ) in the ileal pouch.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Gastrointestinal tract disorders congenital
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON53246

### Source

ToetsingOnline

### Brief title

ENDOPOL

### Condition

- Gastrointestinal tract disorders congenital
- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms benign

### Synonym

Familial adenomatous polyposis (FAP), hereditary colon cancer

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Amsterdam UMC

**Source(s) of monetary or material Support:** KWF

## Intervention

**Keyword:** Adenoma, Chromoendoscopy (dye or virtual), FAP, Pouch

## Outcome measures

### Primary outcome

The primary outcome of this study is the detection of clinical relevant adenomas ( $\geq 5\text{mm}$ ) in the ileal pouch.

### Secondary outcome

Secondary outcomes include:

- Detection of advanced neoplasia in the ileal pouch, defined by advanced adenoma ( $\geq 10\text{mm}$  and/or adenoma with high-grade dysplasia) or cancer.
- Detection of adenomas 1-4mm, 5-9mm and  $\geq 10\text{mm}$  both in the pouch body and rectal remnant with WLE, NBI and dye-based chromoendoscopy
- Number of performed polypectomies
- Chosen interval for next surveillance endoscopy
- Insight Polyposis Staging System (IPSS) score (10)
- Duration of examination
- Incidence of endoscopy-related complications

## Study description

### Background summary

2 - Dye chromoENDoscopy versus virtual chromoendoscopy for assessment of the ileo-an ... 19-06-2025

Familial adenomatous polyposis (FAP) is an inherited gastrointestinal disorder in which patients develop extensive polyps in the colon that, if left untreated, lead to colon cancer. As a preventive measure, patients are endoscopically monitored and the colon is typically removed before the age of 25. This operation can be performed with the possibility of either rectum preservation via ileorectal/ileosigmoidal anastomosis or a pouch procedure. However, polyps can still form in the pouch, remaining rectum, and upper gastrointestinal tract after the operation.

Various modalities are utilized to surveil these patients, including high-definition endoscopy, virtual chromoendoscopy, and dye chromoendoscopy. While both virtual and dye chromoendoscopy have been proven effective in detecting polyps, guidelines currently lack recommendations regarding the preference for a particular modality, and some centers utilize both modalities.

This study aims to examine the difference in adenoma detection through the use of these modalities. Adenomas can develop in the pouch, with the incidence of cancer in the pouch being described as 1-2%. Optimizing endoscopic surveillance techniques in FAP patients is crucial to 1) prevent the development of cancer and 2) avoid the need for a pouch excision.

## **Study objective**

The primary outcome of this study is the detection of clinical relevant adenomas ( $\geq 5\text{mm}$ ) in the ileal pouch.

## **Study design**

This study is designed as an international multi-center randomized controlled trial with an estimated duration of 2 years. Patients will undergo their scheduled regular surveillance pouchoscopy, performed by endoscopists with experience with FAP. Prior to the endoscopy, patients will be randomly assigned to undergo pouchoscopy with dye-based chromoendoscopy or with NBI/BLI (virtual chromoendoscopy). After diagnostic assessment, adenomas with an indication for endoscopic intervention will be removed.

## **Intervention**

Both interventions are standard care for detecting adenomas.

1. Virtual chromoendoscopy
2. Dye chromoendoscopy

## **Study burden and risks**

Both interventions are standard care, and pouchoscopies are not scheduled more

frequently than previously agreed upon for the surveillance of FAP patients.

The standard risks of pouch endoscopy will be considered similar to the risks of colonoscopy:

Gastrointestinal risks:

- Perforation occurs in 4 per 10,000 endoscopies
- Bleeding at biopsy or polypectomy site. A major haemorrhage occurs in 8 per 10,000

Non-gastrointestinal risks

- Sedation-related change in breathing, heart rate and blood pressure
- Pulmonary, cardiovascular, and cerebrovascular complications are rare and are associated with an older age and increasing comorbidity

## Contacts

### **Public**

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### **Scientific**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

Diagnosis of FAP

- Genetic diagnosis: proven APC germline mutation
- Clinical diagnosis: >100 colorectal adenomas in combination with a positive family history of FAP

Have an ileal-pouch anal anastomosis (IPAA)

- After primary proctocolectomy or
- secondary proctectomy after initial colectomy with ileorectal or ileosigmoidal anastomosis (IRA/ISA)

Age  $\geq$  18 years.

## Exclusion criteria

Allergy to indigo carmine (fluid which is used with dye chromoendoscopy).  
Patients who are unwilling or unable to give informed consent.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	10-01-2024
Enrollment:	150

Type: Actual

## Ethics review

Approved WMO	
Date:	21-08-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	06-12-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	30-09-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	14-01-2025
Application type:	Amendment
Review commission:	METC Amsterdam UMC

## 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
CCMO	NL84073.018.23