

Characterization and classification of duodenal adenomas in patients with familial adenomatous polyposis by using narrow band imaging.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON31025

Source

ToetsingOnline

Brief title

CODAN-study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym

Familial adenomatous polyposis, FAP

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W, Olympus Medical Systems Europe ,Olympus Medical Systems, leverancier van endoscopie materiaal

Intervention

Keyword: duodenal polyps, familial adenomatous polyposis, imaging technique, surveillance

Outcome measures

Primary outcome

1. The morphology and vascular pattern of duodenal adenomas will be characterized by NBI and WLE and related to histopathology.
2. Making use of this characterization NBI will be compared to WLE for accuracy in predicting high grade neoplasia and villous architecture.

Secondary outcome

Staging duodenal adenomatosis according to Spigelman's classification will be compared between NBI and WLE.

Study description

Background summary

Familial adenomatous polyposis (FAP) is an inherited autosomal dominant condition, in which multiple gastrointestinal adenomas are found. Aside from colonic polyps, duodenal adenomas have a reported prevalence of nearly 100%. Since these adenomas have a malignant potential, duodenal surveillance endoscopies are recommended to overcome the occurrence of duodenal cancer. Until now, no accurate method has been identified for the detection of patients at high risk for the development of duodenal cancer. We evaluate the use of Narrow Band Imaging (NBI) as a novel endoscopic imaging technique to define groups at high risk for cancer development.

Study objective

The aims of the study are: 1) to characterize the mucosal morphology and vascular pattern of neoplastic and non neoplastic mucosa by NBI and standard White Light Endoscopy (WLE) in the upper gastrointestinal tract; 2) to compare

the accuracy of NBI and WLE for the identification of high grade neoplastic and villous duodenal adenomas; 3) to compare NBI and WLE in staging duodenal adenomatosis according to Spigelman's classification.

Study design

Patients with FAP will undergo an upper endoscopy with WLE, followed by a second inspection with NBI. The stomach will be investigated for fundic gland polyposis and suspicious polyps. In the duodenum the number and size of detected polyps will be noted. Suspicion of duodenal adenomas is based on size > 10 mm, central depression, irregular surface or irregular vascular pattern. Overview and focused WLE and NBI images of all suspicious adenomas and 2 control areas are taken before sampling. Histopathology will be linked to corresponding images. All images are reviewed according to a systematic image evaluation process, consisting of an unblinded assessment of an exploratory set of images and a blinded evaluation of a learning set and validation set. Histopathological outcome will be used as gold standard for diagnosis.

Study burden and risks

In comparison to the procedure for regular patient care, the endoscopy time for study patients takes about 5 minutes longer. Secondly, additional biopsies are taken in study patients, although sampling by a biopsy forceps has no risk for perforation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

APC gene mutation on genetic testing or >100 adenomas during colonoscopy

Exclusion criteria

- 1) non-correctable coagulopathy
- 2) age * 18 years
- 3) inability to give informed consent

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-04-2007

Enrollment: 46

Type: Anticipated

Ethics review

Approved WMO

Application type:

First submission

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	NL16594.018.07