

The risk of colorectal adenomas in patients with duodenal adenomas.

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Study the risk of colorectal adenomas in patients detected with duodenal adenomas.

Ethical review	Approved WMO
Status	Pending
Health condition type	Benign neoplasms gastrointestinal
Study type	Observational invasive

Summary

ID

NL-OMON30631

Source

ToetsingOnline

Brief title

The risk of colorectal adenomas in patients with duodenal adenomas.

Condition

- Benign neoplasms gastrointestinal

Synonym

adenoma, polyp

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: adenoma, colon, duodenum, surveillance

Outcome measures

Primary outcome

The risk of colonic adenomas is calculated.

The risk of colonic adenomas in the study group is compared with a group of patients screened for livertransplantation with gastroduodenoscopy and colonoscopy in the same period. In this control group patients are excluded with a disease with an increased risk of coloncancer (i.e. Primary biliary cholangitis).

Secondary outcome

no secondary parameters

Study description

Background summary

Colorectal cancer is the third most common cancer and the second most common cause of cancer related deaths. Most cases of colon cancer begin as small adenomatous polyps. Through colonoscopic examinations these adenomas can be detected and subsequently removed. It is generally accepted that, like colorectal adenomas, duodenal adenomas also follow the adenoma-carcinoma sequence. Curiously, despite numerous phenotypic similarities between the small and large intestinal epithelia, including a very high cellular turnover, small intestinal neoplasia is very rare compared with its colorectal counterpart [1].

In the known hereditary colon cancer syndromes, patients are at increased risk of small bowel adenomatosis/cancer besides their generally high risk of colorectal adenomas/cancer. For instance, in 40-90% of patients with familial adenomatous polyposis (FAP) duodenal adenomatosis is found (2-6). These adenomas are mainly situated around the ampulla Vateri. The lifetime risk of developing duodenal cancer in FAP is 3-4% at the age of 70 (7). Most polyposis patients develop hundreds of colorectal adenomas and without prophylactic colectomy they inevitably develop colon cancer (8). Also in other hereditary colon cancer syndromes (MUTYH-associated polyposis and hereditary non-polyposis

colorectal cancer) gene carriers have an increased risk of small bowel adenomas/cancer besides their high risk of colonic adenomas/cancer.

Sporadic duodenal adenoma is an uncommon finding. In a large Scandinavian study only 0.4% of 584 endoscopy patients had duodenal polyps, of which 7% were adenomatous [9]. Most adenomas are found incidentally at endoscopy. To date, it is unknown whether this group of patients is, like gene carriers in the hereditary colon cancer syndromes, at increased risk of colorectal adenomas. Several retrospective studies suggest an increased risk of colorectal neoplasia in patients with duodenal adenomas. In a recent study, 73% of patients with duodenal adenomas and without familial adenomatous polyposis had colonic adenomas [11-13]. Also small intestinal carcinoma is associated with colorectal carcinoma and vice versa [10]. However, the extent to which duodenal adenomas are associated with colorectal adenomas is not well prospectively studied.

In conclusion, an increased risk of colonic adenomas (and thus of colon cancer) in patients with duodenal adenomas is likely. Therefore, the risk of colonic adenomas in this group of patients should be calculated in order to advise these patients whether they should undergo endoscopic examinations of their colon. Because duodenal adenomas are an uncommon finding, a multicenter trial should answer this question.

References

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Study objective

Study the risk of colorectal adenomas in patients detected with duodenal adenomas.

Study design

Prospectively collected data in three hospitals (Slotervaart Hospital Amsterdam, University Medical Center Groningen, Leiden University Medical Center).

Study burden and risks

If during colonoscopy polyps are detected, they will be removed if possible. If a polyp is removed there is a small chance of bleeding or perforation. The estimated risk of a complication is about 0.2%.

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

Patient with a by chance detected duodenal adenoma during upper gastrointestinal endoscopy.

Exclusion criteria

- 1) Patients known with familial adenomatous polyposis.
- 2) Patients known with MUTYH-associated polyposis coli.
- 3) Patients known with hereditary non polyposis colorectal cancer

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-01-2007
Enrollment: 100
Type: Anticipated

Medical products/devices used

Generic name: colonoscopy
Registration: Yes - CE intended use

Ethics review

Approved WMO
Application type: First submission
Review commission: METC Leids Universitair Medisch Centrum (Leiden)

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	NL14980.058.07