Interlaboratory variability in the grading of dysplasia and morphology of duodenal adenomas in a nationwide cohort.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24042

Source
NTR

Brief title
Interlab FAP

Health condition

Familial adenomatous polyposis (FAP), attenuated FAP, MUTYH-adenomatous polyposis (MAP).

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Dysplasia grading

Secondary outcome

Morphology grading

Study description

Background summary

Rationale
Familial adenomatous polyposis (FAP) patients face an increased risk of duodenal polyposis of up to 90% at age 70. Moreover, FAP patients face an increased cumulative risk of duodenal cancer of 2-5%. Endoscopic duodenal surveillance starting at the age of 25-30 is recommended to prevent duodenal cancer. The frequency of surveillance is determined in accordance to the Spigelman classification, which measures the severity of duodenal polyposis. Histopathologic variables are an important part of the Spigelman classification, as two of the four components are based on histopathological outcomes. Especially dysplasia grading seems to be an important factor in determining the risk of duodenal cancer. However, since a grading system for dysplasia and morphology of duodenal lesions is missing these lesions are classified according to guidelines for colorectal lesions. This might lead to an increased interlaboratory variability, resulting in variance in risk stratification between different health care providers.

Main objective
The aim of this study is analyse the interlaboratory variability in the grading of dysplasia of duodenal adenomas in daily practice, in a nationwide cohort.

Study design
All histopathological reports of duodenal adenomas from patients with a history of FAP and/or a history of (sub)total colectomy from 1991 - 2019 will be identiefied from the Dutch Pathology Registry (PALGA). The proportion of adenomas with high-grade dysplasia will be determined and compared between all laboratories.

Study population
Patients with a history of FAP and/or a history of (sub)total colectomy who have (a) histopathological report(s) on duodenal adenomas.

Main study parameters
Dysplasia grading, morphology grading.

Study objective

There is considerable interlaboratory variation in the grading of dysplasia in duodenal adenomas.

Study design

None

Contacts

Public
Radboudumc
Elsa Soons

0650000996
Scientific
Radboudumc
Elsa Soons

0650000996

Eligibility criteria

Inclusion criteria

- Patients with a FAP/AFAP/MAP diagnosis or with a history of a (sub)total colectomy prior to duodenum tissue sampling
- Duodenal biopsy/polypectomy between 1991 - 2019

Exclusion criteria

- No duodenal specimen between 1991 - 2019

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-06-2020
Enrollment:	1000
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL8757
Other	the Dutch Pathology Registry (PALGA) : 2020-41

Study results