Gastric fundic gland polyps in patients undergoing routine upper gastrointestinal endoscopy

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1. To determine the prevalence of gastric fundic gland polyps in patients undergoing routine upper gastrointestinal endoscopy2. To determine the prevalence of dysplasia in these gastric fundic gland polyps3. To determine the prevalence of gastritis...

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

Summary

ID

NL-OMON30802

Source
ToetsingOnline

Brief title
FGP-ROUGAS

Condition

- Benign neoplasms gastrointestinal

Synonym
gastric fundic gland polyps

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: fundic gland polyps, gastritis, Helicobacter pylori, stomach

Outcome measures

Primary outcome

Description of

- the prevalence of gastric fundic gland polyps in this population

- the prevalence of dysplasia in these gastric fundic gland polyps

- the prevalence of gastritis, atrophy, intestinal metaplasia, dysplasia and

Helicobacter pylori

- the serum levels of gastrin, pepsinogen I and II, and anti-Helicobacter

pylori antibodies.

- the results of the questionnaire assessment

Secondary outcome

not applicable

Study description

Background summary

Gastric fundic gland polyps are benign gastric polyps that initially were described in association with Familial Adenomatous Polyposis Coli (FAP), in which these polyps are found in 40-60% of the patients. Later, these polyps were recognized to occur sporadically, which is now their most common presentation. In literature, gastric fundic gland polyps are described in 0.5 - 5 % of upper endoscopy procedures, with varying prevalences depending on the study population. The prevalence of gastric fundic gland polyps seems to be increasing, but this could be explained by co-factors such as the use of different nomenclatures of gastric polyps and the progress in videoendoscopy. The pathogenesis and etiology of gastric fundic gland polyps is still unclear. In some studies, a positive association with the use of protonpumpinhibitors was found, while in other studies this association could not be confirmed.

Several studies have described a negative association between gastric fundic gland polyps and infection with Helicobacter pylori, but the reason remains unclear. There seems to be no association between gastric fundic gland polyps and several types of gastritis.
Unlike in FAP-associated gastric fundic gland polyps, dysplasia is seldomly found in sporadic gastric fundic gland polyps. The two types of polyps are histologically similar but genetically different, with mutations in the APC-gene in the FAP-associated polyps and mutations in the beta-catenin gene in the sporadic ones.
The occurence of sporadic gastric fundic gland polyps seems to be associated with an increased incidence of colorectal adenomas. The impact of this finding is still unclear and it can not be stated yet that a colonoscopy should be performed when gastric fundic gland polyps are detected.

Study objective

1. To determine the prevalence of gastric fundic gland polyps in patients undergoing routine upper gastrointestinal endoscopy
2. To determine the prevalence of dysplasia in these gastric fundic gland polyps
3. To determine the prevalence of gastritis, atrophy, intestinal metaplasia, dysplasia, Helicobacter pylori in patients with and without fundic gland polyps
4. To obtain information about demographic factors, medical history, history of familial diseases, medication, other intoxications and symptoms in patients with and without fundic gland polyps
5. To obtain information about the serum levels of gastrin, pepsinogen I and II, and anti-Helicobacter pylori antibodies in patients with and without fundic gland polyps.

Study design

All patients undergoing a routine upper gastrointestinal endoscopy will receive a letter explaining the aim and procedure of the study. An informed consent form is included in this letter.
All patients with signed informed consent in whom gastric fundic gland polyps are found, will be included as well as the next two patients in the endoscopy programme who do not have gastric fundic gland polyps.
During the endoscopy, 2 gastric antrum and 2 gastric corpus biopsies will be taken as well as 1 or 2 biopsies from the found polyps. In the polyp material, the histopathological diagnosis will be checked as well as the presence and grade of dysplasia in these polyps. In the gastric biopsy specimens the presence and grade of gastritis, atrophy, dysplasia and intestinal metaplasia will be checked as well as the presence of Helicobacter pylori.
After the endoscopy, the patients will be asked to fill out a questionnaire with questions regarding symptoms, medication, intoxications, medical history and history of familial diseases. In addition, a venous blood sample will be obtained in which gastrine and pepsinogen I and II will be measured, as well as

anti-Helicobacter pylori antibodies.

Study burden and risks

There are no risks associated with participation in this study, neither will patients benefit from it. The burden of participation consists of a lengthening of the upper gastrointestinal endoscopy with at most 2 minutes, the questionnaire assessment and the obtaining of the venous blood sample.

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

age > or = 18 years

signed informed consent
cases: endoscopical presence of gastric fundic gland polyps
controls: no endoscopical presence of gastric fundic gland polyps

Exclusion criteria

coagulation disorder
use of warfarin or other anti-coagulant medication if uncorrected at the time of endoscopy
liver cirrhosis

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-05-2007
Enrollment:	900
Type:	Actual

Ethics review

Approved WMO

Date:	09-01-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL13536.078.06