An observational study on the presence of inflammatory changes in the mucosa of the sigmoid colon in asymptomatic individuals with diverticular disease and the correlation with colon microbiology

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The primary objective is to evaluate the presence of inflammation in the mucosa around diverticula in the sigmoid colon in patients without clinical symptoms of diverticular disease and without endoscopic evidence of inflammation. This is compared...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Diverticular disorders
Study type	Observational invasive

Summary

ID

NL-OMON36560

Source
ToetsingOnline

Brief title
PADIFLORA study

Condition

- Diverticular disorders

Synonym
Diverticular disease, diverticulosis

Research involving
Human

Sponsors and support

Primary sponsor: Kennemer Gasthuis
Source(s) of monetary or material Support: Postumus Meyes Fonds Kennemer Gasthuis

Intervention

Keyword: Aetiology, Colonic microbiology, Diverticular disease, Histology

Outcome measures

Primary outcome

Inflammation, defined as mean T lymphocyte count and neutrophil count in the

mucosa of the colon.

Secondary outcome

Colonic flora, expressed as anaerobic/ aerobic ratio and presence or absence of

certain strains of bacteria by means of micro-array.

Study description

Background summary

Approximately 10 to 25% of patients with diverticular disease will eventually develop an episode of acute diverticulitis. The pathogenesis of diverticulitis remains unclear. Rather than the original hypothesis that all forms of diverticulitis arise from a microperforation, recent research shows that chronic low-grade inflammation caused by an altered colonic flora may play a role.

Study objective

The primary objective is to evaluate the presence of inflammation in the mucosa around diverticula in the sigmoid colon in patients without clinical symptoms of diverticular disease and without endoscopic evidence of inflammation. This is compared to other parts of the colon not affected by diverticula and to pathology specimens taken from the sigmoid colon mucosa of individuals without diverticulosis on colonoscopy. Furthermore we will evaluate the correlation between mucosal inflammation and colonic microbiology.

Study design

The proposed study is an observational study in which a cohort of patients with endoscopy confirmed diverticulosis is compared to a cohort of patients without diverticulosis at endoscopy.

Study burden and risks

There is no specific benefit for individual patients in this study as it involves fundamental research on the pathogenesis of diverticular disease and diverticulitis that may guide further research on prevention and treatment. The risk associated with taking biopsies is considered low. Bleeding and perforation are the two main concerns. Some form of rectal blood loss after biopsy is reported in 0.2% to 3,4% of patients of which 0,1% required admittance to the hospital. Perforation is very rare with incidences ranging from 0.07% to 0.72% in all colonoscopies. To minimize the risk of bleeding, patients with anti-coagulant medication are excluded from participation in our study.

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

• Eighteen years or older;
• Scheduled for colonoscopy for:
1. Hematochezia;
2. gastrointestinal hemorrhage;
3. unexplained changes in bowel habit;
4. weight loss;
5. iron-deficiency anemia;
6. chronic obstipation without positive reaction on the treatment;
7. screening for and follow-up of colorectal cancer;

Exclusion criteria

• Suspicion of diverticular related complaints;
• Proven history of symptomatic diverticular disease;
• Use of coumarin derivates, unless stopped one week before colonoscopy;
• Use of NSAID*s unless stopped one week before colonoscopy;
• Use of platelet aggregate inhibitors, including aspirin, unless stopped one week before colonoscopy;
• Sedation before informed consent;
• History of inflammatory bowel disease;
• Endoscopic signs of inflammation.

Study design

Design

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

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	17-01-2011
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL32966.094.10