Precancerous abnormalities in patients with diverticular disease

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With this study we want to investigate the possible correlation between pre malignant abnormalities in the colon and inflamation of the colonic mucosa in patients with long lasting (more than 8 years) diverticular disease.Patients included will...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Diverticular disorders
Study type	Observational invasive

Summary

ID

NL-OMON38599

Source
ToetsingOnline

Brief title
Precancerous abnormalities in diverticular disease

Condition

- Diverticular disorders

Synonym
Diverticular disease, diverticulitis and diverticulosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Colon, Diverticulitis, Diverticulosis, Precancerous

Outcome measures

Primary outcome

This study aims to evaluate the possible interaction between chronic

inflammation and precancerous lesions in diverticular disease.

Secondary outcome

Secondary Objectives:

Semi-quantitative scoring for

* Dysplasia

o No dysplasie

o Indefinite for dysplasia

o Low grade dysplasia

o High grade dysplasia

* Inflammation (active and chronic)

o 0 = normal looking (round nuclei) infiltrate of the lamina propria, with a

cell distribution gradient towards basal

o 1= loss of gradient (because more cells are located basely)

o 2 = loss of gradient and presence of neutrophil granulocytes

o 3 = loss of gradient and ulceration in combination with/or presence of crypt

abscesses

* Apoptosis

o 0 = 0 or 1 apoptotic cell per biopsy

o 1 = more than 1 apoptotic cell per biopsy

* Fibrosis

o 0 = no fibrosis

o 1 = presence of fibroses

Using immunohistochemical staining, cases indefinite for dysplasia will be

evaluated by

* MIB1

* P53

Study description

Background summary

The available literature regading the influence of chronic diverticular disease on the colonmucosa is not ambigious. These are some studies stating to have found increased rates of (pre) malignant abnormalies in patietns with chronic diverticular disease.

Chronic inflammation can seriously effect the quality of the colonic mucosa. Long term inlfammation in the colon is known to influence normal cellular structure in a negative way. Which coul ultiimately lead to the presence of high grade dysplasia and colorectal cancer.

The possible sequelea of chronic inflammation in patients with inflammatoire bowel disease are well recorded. As patients with Crohns disease and/or Colitis Ulcerosa are screened for the presence of colorectal carcinoma. The guidelines state that specialists should commence screening an average 8 years after diagnosis has been made, depending on disease activity.

Study objective

With this study we want to investigate the possible correlation between pre malignant abnormalities in the colon and inflamation of the colonic mucosa in patients with long lasting (more than 8 years) diverticular disease.

Patients included will undergo sigmoidoscopy or colonoscopy and bioptes will be taken from three portions of the end of the colon. These biopties will be scored by two independents skilled patholog

We hypothesise to find a positive correlation between severity of mucosa inflammation and grade of colonic mucosa dysplasia. When such a correlation is found more research regarding this subject is neccesary.

Study design

After H&E staining, semi-quantitative scoring for dysplasia, inflammation (active and chronic), apoptosis and fibrosis is performed. Cases indefinite for dysplasia will be evaluated by MIB1 and p53

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Study burden and risks

Very slightly increased risk of a perforation of the colon.

In patients with long lasting diverticulitis an increased chance of developing (pre)cancerous lesions could be present. Histological evaluation of tissue from a site in chronic inflammation could show us if the risk of malignant transformation is increased in these patients.

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

Informed consent (IC)
Patients undergoing a colonoscopy/sigmoidoscopy

Exclusion criteria

Refusal of participation
Inflammatory bowel disease
A medical history of colorectal cancer or pre-maligmant polyp(s)
Previous surgery of the colon
History of familial colon 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:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	42
Type:	Anticipated

Ethics review

Approved WMO

Date:	30-10-2013
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	NL44351.029.13