Endoscopic detection of small bowel dysplasia and cancer in patients with jejunoileal Crohn*s disease :prospective study in a cohort of high risk patients

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Early detecting of dysplasia and adenocarcinoma in patients with long excisting crohn's disease.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON37771

Source
ToetsingOnline

Brief title
Dysplasia study

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease, Inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: GETAID

Intervention

Keyword: cancer, dysplasia, M. Crohn, small bowel

Outcome measures

Primary outcome

To determin the frequency of small bowel dysplasia and adenoma carcinoma by endoscopy with biopsies in a population of Crohn's disease patients with a high risk of dysplasia and adenomacacinoma due to a disease history of more than ten years.

Secondary outcome

1.2.1. Evaluation of the feasibility of endoscopic surveillance defined as success rate of reaching the small intestine lesions endoscopicly and to collect biopsies

1.2.2. Evaluation of the importance of indigo carmine colouring for diagnosis of dysplasia and cancer of the small intestine

1.2.3. Determination of the factors associated with the presence of dysplasia and cancer.

1.2.4. Evaluation of the complication caused by the endoscopic procedures and biopsies

Study description

Background summary

Adenoma of the small intestine is rare and represents 2% of the digestive cancers. The disease appears more often in patients with crohn*s diseaese. Recent meta analysis of 9642 patients showed a relative risk of adenoma carcinoma of the small intestine of 28.4 compared with the regular population.

The risk has increased in patients with exclusive small intestine involvement (relative risk 58.5).
The average survival time after diagnosis is 28 months. One of the reasons for this bad prognosis is the late stage in which the diagnosis is made. Often the diagnosis is made after resection, because the clinical symptoms and radiology findings of a adenoma carcinoma of the small intestine are similar to inflammatory stenosis.
In analogy with the surveillance strategy for dysplasia in patients with ulcerative colitis and crohn*s disease of the colon, a screening of the small intestine in long existing crohn*s disease should be very effective to locate the disease.

Study objective

Early detecting of dysplasia and adenocarcinoma in patients with long excisting crohn's disease.

Study design

Study with an international prospective cohorte.

Study burden and risks

There is no extra burden of risk for patients participating in this study. When a patient decides not to participate he/she will also undergo a endoscopy with biopsies as part of their regular patient care.

Contacts

Public
Academisch Medisch Centrum

meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 18 years or older
- M. Crohn of the jejunum and/or ileum with or without other involved areas of the gastrointestinal system
- Lesions of the small intestine which exist for at least 10 years (patient with a ileocolonic anastomosis with isolated ileal lesions for more than 10 years may be included, but this sub group may only be 30% of the included patients).
- Crohn lesions accessible by endoscopy
- CT scan or MRI of the small intestine in the last 12 months to locate the lesions.
- Signed informed consent

Exclusion criteria

- History of dysplasia or cancer of the small intestine
- Contra-indication for an endoscopy
- Not willing to participate
- Pregnancy
- Participating in an other clinical trial

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-04-2013
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	17-12-2012
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
ClinicalTrials.gov	NCT01180452
CCMO	NL40151.018.12