

Survey: Patient Knowledge and Preferences in Regards to Colorectal Cancer in the Setting of Ulcerative Colitis

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1.What are ulcerative colitis patients* understanding of their risk of colon cancer and the benefit of colonoscopy?2. What is ulcerative colitis patients* threshold of cancer risk before accepting colectomy in the setting of dysplasia?3. What are...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal infections
Study type	Observational non invasive

Summary

ID

NL-OMON30474

Source

ToetsingOnline

Brief title

Ulcerative Colitis Survey: A patient perspective

Condition

- Gastrointestinal infections
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym

colitis, Inflammatory Bowel Disease (IBD)

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Colorectal Cancer, patient, Survey, Ulcerative Colitis

Outcome measures

Primary outcome

Our primary endpoint is misperception of the risk of coloncancer. Misperception is defined as an incorrect understanding of the risk of coloncancer, which is not consistent with the numbers mentioned in the literature.

Secondary outcome

Our secondary endpoints are 1) misperception of the benefits of surveillance colonoscopy and 2) ulcerative colitis patients* threshold of cancer risk before accepting colectomy in the setting of dysplasia. Misperception is here also defined as an incorrect understanding of the real benefits of colonoscopy.

Study description

Background summary

There is uncertainty of the risk of colorectal cancer in the setting of ulcerative colitis, the efficacy of surveillance colonoscopy, and the appropriate management of low-grade dysplasia. Patients with Ulcerative colitis(UC) have a sufficient increased risk of developing malignancy. It accounts for one sixth of all deaths in UC patients. The exact magnitude of the risk has remained a bit controversial in the past due to various biases and methodological errors in published studies. At the moment the risk of CRC in patients with Ulcerative colitis is estimated to be 2% after 10 years, 8% after 20 years and 18% after 30 years of disease.

The risk of colorectal carcinoma is increased in patients with extensive ulcerative colitis of long duration. Patients with disease extending to the hepatic flexure or more proximally have the greatest risk of CRC. Further risk factors include primary sclerosing cholangitis and a family history of sporadic

colorectal cancer. The risk also varies with geography. Incidence rates for CRC are higher in de USA and the UK compared to Scandinavia and other countries.

There are no available data on ulcerative colitis patients* understanding of their risk of colon cancer, their perceptions of the benefits of colonoscopy, or the threshold at which their risk of colon cancer is high enough to warrant colectomy.

Our hypothesis is that patients with ulcerative colitis misperceive their risk of colon cancer and the benefit of colonoscopy. Patients* threshold for colectomy in the setting of dysplasia will vary based on their perceptions of risk and on individual patient characteristics.

Study objective

- 1.What are ulcerative colitis patients* understanding of their risk of colon cancer and the benefit of colonoscopy?
2. What is ulcerative colitis patients* threshold of cancer risk before accepting colectomy in the setting of dysplasia?
3. What are patient and disease characteristics that predicts patient knowledge and their threshold for colectomy in the setting of dysplasia?

Study design

Questionnaire

Study burden and risks

Patients are asked to complete a survey. Completing the survey will take approximately 30 minutes. It's anonymous and voluntary and there are no risks involved for the 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

- Patients diagnosed with ulcerative colitis by established criteria
- At least 8 years of disease
- Ages 18 to 70 inclusive

Exclusion criteria

- No history of colectomy
- No history of colorectal cancer
- No history of other cancers (except non-melanoma skin cancer)

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 11-07-2007
Enrollment: 200
Type: Actual

Ethics review

Approved WMO
Date: 31-05-2007
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	NL16309.078.07