

Perianal and anorectal complications in patients with inflammatory bowel disease in time

Published: 08-10-2009

Last updated: 06-05-2024

1.To prospectively evaluate the course of anorectal function in IBD patients with perianal lesions
2.To establish potential biomarkers to predict the course of anorectal function in IBD patients with perianal lesions

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anal and rectal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON33522

Source

ToetsingOnline

Brief title

Anorectal function in IBD patients

Condition

- Anal and rectal conditions NEC

Synonym

complications around the anal area, perianal complications

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Research Budget MDL VUmc

Intervention

Keyword: anus diseases, follow-up study, inflammatory bowel disease, rectal diseases

Outcome measures

Primary outcome

- Changes of anorectal pressures assessed by anal manometry, rectal compliance measurement and anal endosonography

- Clinical symptoms:

- * faecal incontinence measured by Vaizey and Wexner scores

Secondary outcome

- Prognostic factors of alteration of anorectal function using the Montreal

classification (age, location, behavior and perianal disease), gender, surgery,

family history of IBD and smoking habit.

- Quality of life measured by QLQ-SF36 and IBDQ, and the morbidity caused by

perianal Crohn's disease measured by PDAI

Study description

Background summary

Crohn's disease (CD) and ulcerative colitis (UC) form part of the group idiopathic chronic inflammatory bowel diseases (IBD). Perianal lesions are an important clinical feature of CD. Less is known about the correlation between perianal lesions and UC. A high prevalence of perianal complications in UC patients has been described before 1966 due to the fact that those patients may likely had CD instead of UC. However, it is apparent that patients with clear cut UC may suffer from perianal problems.

It is not clear why some patients develop perianal lesions and others do not.

To understand more about the pathophysiology of perianal lesions, anorectal function may play a role. Data about anorectal pressures are conflicting.

Altered anorectal pressures appear to be diminished in many patients with CD.

One study showed an increased anal pressure and rectal sensitivity in patients

in absence of anorectal inflammation, which can compromise the anal circulation. This may increase infection risk in the anal region and the development of fistulas. Contrastingly, in a previous study, we showed a statistically significant lower maximum resting pressure in CD patients compared with healthy volunteers.

Study objective

- 1.To prospectively evaluate the course of anorectal function in IBD patients with perianal lesions
- 2.To establish potential biomarkers to predict the course of anorectal function in IBD patients with perianal lesions

Study design

All patients with IBD and complaints of perianal function and anorectal dysfunction were analyzed by means of anorectal function tests and anal ultrasound in the period 1993-1999. In total 56 patients underwent anorectal function tests.

These patients will be approached to fill in a questionnaires concerning quality of life and anorectal function. They will be invited for a follow-up perianal examination and anorectal function investigation. These test results will be compared with the first test results.

Study burden and risks

No specific ethical problems exist. Patients will be informed about the study and asked for consent. Some patients may feel uncomfortable about answering questions regarding incontinence. To reduce this problem, the questionnaires will be sent to the patients to be filled in private setting.

The anorectal examinations are easy to perform and well tolerated by patients. It requires no bowel preparation. The investigation takes only a few minutes.

Anorectal function tests and EUS can be considered as a safe, economic procedure. Furthermore, all patients had these test previously.

In addition, patients with complaints can be seen in our outpatient clinic to consider treatment.

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 with IBD who had at least one anorectal function test between 1993-1999 in our Department of Gastroenterology

Exclusion criteria

Females who are pregnant or had a delivery < 6 months.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 08-04-2010

Enrollment: 56

Type: Actual

Ethics review

Approved WMO

Date: 08-10-2009

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

CCMO

ID

NL28067.029.09