The Effect of Appendectomy on the Clinical Course of Ulcerative Colitis, the ACCURE trial.

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Laparoscopic appendectomy ameliorates the disease course and prevents colectomies, corticosteroid use and immunomodulation in newly diagnosed ulcerative colitis.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22414

Source
NTR

Brief title
ACCURE-trial

Health condition

Ulcerative Colitis, Inflammatory Bowel Disease

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: initiator = sponsor

Intervention

Outcome measures

Primary outcome

The one year cumulative UC relapse rate (defined both clinically and endoscopically as Mayo-score ≥5 with endoscopy score of 2 or 3).

Secondary outcome

1. Number of relapses per patient;
2. Time to first relapse;
3. Health related quality of life and costs (EQ-5D, EORTC-QLQ-C30-QL and IBDQ);
4. Disease activity, as measured with the Mayo score;
5. Number of semesters in remission since beginning of disease and current relapse;
6. Number of colectomies.

Study description

Background summary

The suspicion of an inverse relationship between ulcerative colitis (UC) and appendectomy originates from the observation in 1987 that the rate of prior appendectomy was significantly lower in UC patients compared to healthy controls. Since then, evidence has been accumulating indicating that the appendix has an immunomodulatory role in ulcerative colitis. Several case series have reported on the reduction of colectomy rates following appendectomy in UC patients. If an appendectomy can protect diagnosed UC patients from future steroid usage, immunosuppression and colectomy, this simple intervention may improve the course of the disease and the quality of life in these patients tremendously and reduce costs for medications and surgeries to an important extent. The annual incidence of ulcerative colitis amounts to 6-8 new cases per 100,000. The majority of these patients currently needs lifelong treatment with medication including biologicals and 10-20 per cent of the patients requires colectomy within one year. Up to 30%-40% of patients with UC ultimately require surgery. The purpose of the current study is to assess prospectively whether laparoscopic appendectomy alters the course of ulcerative colitis and to study histological and immunological characteristics of the resected appendices from UC patients compared to several control groups. The study is a multicenter study comparing patients between 18 and 80 years with newly diagnosed mild to moderate ulcerative colitis that have been treated medically for their first relapse with 5–ASA preparations and/or corticosteroids. Once clinical and endoscopic remission has been attained, patients will be randomized (1:1) to undergo an elective and ambulatory laparoscopic appendectomy in day care setting. The primary endpoint is the one year cumulative UC relapse rate in both groups.

Study objective

Laparoscopic appendectomy ameliorates the disease course and prevents colectomies, corticosteroid use and immunomodulation in newly diagnosed ulcerative colitis.

Study design

Both patient groups will be followed for one year. In the 2nd half 2012 the clinical study will start, the total inclusion is scheduled to take place within 2 years.

Intervention

Elective laparoscopic appendectomy in day care setting.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age in between 18 and 60 years;
2. Established diagnosis of ulcerative colitis, diagnosed less than 1 year prior to randomisation (any extent of disease);
3. Recent disease relapse less than 4 months prior to randomisation medically treated until remission;
4. Treatment of UC only with 5-ASA (oral and/or topical) and/or with a maximum of 1 steroid course;
5. Clinical (Mayo score <3) and endoscopic (Mayo score 0 or 1) remission;
6. Negative stool culture (including Gonorrhea and Chlamydia);
7. Obtained written informed consent.

Exclusion criteria

1. Prior appendectomy or other abdominal surgery;
2. Any suspicion of Crohn's disease;
3. Severe colitis (defined as: disease treated with immunomodulators or biologicals, disease not reactive to a maximum of one course of steroids, remission not achieved by steroids and 5-ASA therapy in <=8 weeks, disease requiring hospitalisation, toxic megacolon);
4. Patients with active extra-intestinal infections, liver or kidney failure, mayor lung and heart co-morbidity;
5. Insufficient command of Dutch or cognitively unable to complete Dutch questionnaires.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2011
Enrollment:	182
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-05-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 53054
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2745
NTR-old	NTR2883
CCMO	NL37531.018.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON53054

Study results

Summary results
N/A