The effect of appendectomy on the clinical course of Ulcerative colitis: a randomized multicenter trial

Published: 03-11-2011
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The objective of this study is to evaluate the short-term and medium-term effectiveness of appendectomy to maintain remission in patients with an established diagnosis of ulcerative colitis treated for a relapse, but never treated with biologicals.

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

Summary

ID

NL-OMON53054

Source
ToetsingOnline

Brief title
ACCURE trial

Condition

- Gastrointestinal inflammatory conditions

Synonym
inflammatory bowel disease, Ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: NutsOhra,Dr. Falk Pharma GmbH

Intervention

Keyword: appendectomy, disease course, inflammatory bowel disease, ulcerative colitis

Outcome measures

Primary outcome

1. The one year 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 (EQ-5D, EORTC-QLQ-C30-QL, IBDQ and a 'global

change question').

4. Disease activity, as measured with fecal calprotectin and the Mayo score.

5. Number of colectomies

Study description

Background summary

The annual incidence of ulcerative colitis (UC) amounts to 6-8 new cases per 100,000. Patients are intentionally treated medically and colitis refractory to medical management is treated surgically, mostly by means of an emergency colectomy or elective proctocolectomy with ileal J-pouch anastomosis. Over the past 10 years evidence has been accumulating indicating that the appendix has an immunomodulatory role in patients with UC reducing the need for medication and even colectomy. The concept that appendectomy may modulate the disease avoiding medical and surgical treatment, and costs is very appealing and exciting. This is especially true for appendectomy, as this is a relatively simple procedure that can be performed in day care.

Study objective

The objective of this study is to evaluate the short-term and medium-term

effectiveness of appendectomy to maintain remission in patients with an established diagnosis of ulcerative colitis treated for a relapse, but never treated with biologicals.

Study design

The design of the study is a multicenter prospective randomised study.

Intervention

Patients will be randomized to laparoscopic appendectomy or to no appendectomy in day care setting.

Study burden and risks

Both groups of patients will be followed for one year by the medical staff and trial nurses in order to monitor morbidity of treatment, use of medication or necessity of surgery, disease activity as measured by endoscopy (at inclusion and after 12 months) and the non-invasive 9-point partial Mayo score (after 3, 6, 9 and 12 months), Health related Quality of life as measured by the EQ-5D, EORTC-QLQ-C30-QL, IBDQ (at inclusion and every 3 months thereafter), aglobal change question* will be asked at 12 months follow- up (*Since the start of the study, have your UC symptoms improved overall?*), questionnaires, utilization of health care, direct medical and non-medical costs and friction costs related to leave from work. Patients will be contacted by telephone every 3 months by a trial nurse to assess medication usage, complications, additional interventions, re-admissions, duration of hospital stay and visits to the outpatient clinic, number of days of sick leave and of social in attendance and to ensure completions of the questionnaires.
Patients will minimally be followed up by the gastroenterologist or the research resident at the outpatient clinic or per telephone at 6 weeks and 3, 6, 9 and 12 months after inclusion, other visits are scheduled on indication. At the end of the study period, after 12 months, a second colonoscopy will be performed to assess mucosal healing. In the 5 years following the study the gastroenterologists will be asked to measure the non-invasive 9-point partial Mayo score every 6 months during outpatient clinic appointments.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Aged 18 years and older
- Established diagnosis of ulcerative colitis (any extent of disease)
- Disease relapse within 12 months of randomisation medically treated until remission
- Clinical (Mayo score <3) and endoscopic (Mayo score 0 or 1) remission
- Obtained written informed consent

Exclusion criteria

- Prior appendectomy or other major abdominal surgery precluding safe appendectomy
- Any suspicion of Crohn's disease
- Disease recently treated with biologicals within 3 months prior to inclusion
- Severe disease ever treated with biologicals and stopped due to secondary non-response
- Toxic megacolon or severe ongoing colitis at time of randomimsation
- Patients with active extra-intestinal infections, liver or kidney failure, mayor lung and heart co-morbidity.
- 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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-09-2012
Enrollment:	154
Type:	Actual

Ethics review

Approved WMO Date:	03-11-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-09-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-09-2012

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-02-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-11-2019

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-06-2021
Application type:	Amendment
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

ID: 22414
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL37531.018.11
OMON	NL-OMON22414