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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22414

Bron
NTR

Verkorte titel
ACCURE-trial

Aandoening

Ulcerative Colitis, Inflammatory Bowel Disease

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The one year cumulative UC relapse rate (defined both clinically and endoscopically as Mayo-

score ≥5 with endoscopy score of 2 or 3).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

Elective laparoscopic appendectomy in day care setting.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2011
Aantal proefpersonen:	182
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-05-2011

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 53054
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A