ASSESSMENT OF THE PERFORMANCE OF THE PILLCAM COLON CAPSULE IN CROHN‘S DISEASE BEFORE AND AFTER TREATMENT WITH ANTI-TNF

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

Samenvatting

ID

NL-OMON22197

Bron
NTR

Verkorte titel
Pillcam 2

Aandoening

Crohn's disease, ziekte van Crohn

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam
Overige ondersteuning: Given Imaging, Israel.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Sensitivity of PCCE2 to detect mucosal changes after treatment with the anti-TNF agents (Infliximab or Adalimumab).

Toelichting onderzoek

Achtergrond van het onderzoek

The goals of treatment in Crohn’s disease have evolved in recent years from symptom control to healing of mucosal lesions, usually visualized by endoscopy. Potent therapeutic agents, such as anti-TNF agents, have made restoration of mucosal integrity attainable in a significant proportion of patients. Moreover, anti-TNF therapy was shown to be more effective in patients that had visible ulcers on endoscopy than in patients without such lesions. This means that clinicians are recommended to check for the presence of ulcers before they embark on biological therapy. Finally, endoscopic evaluation of treatment effects in Crohn’s disease has entered routine practice. However, endoscopic procedures are time consuming, invasive and unpleasant for the patient. Surrogate markers for the severity of inflammation such as faecal calprotectine are under investigation. Magnetic resonance enterography was shown to nicely parallel with the severity of inflammation seen at endoscopy, but also this diagnostic tool is expensive and time consuming.
The development of a simple alternative to optical colonoscopy to assess mucosal inflammation in patients with Crohn’s disease would therefore be of extreme importance. A reliable Pillcam examination is high on the priority list of potential options.
Recently, a multicenter study was performed that assessed safety and feasibility of PCCE-2 in evaluating the severity of mucosal inflammation in patients with ileocolonic Crohn's disease (1). Substantial agreement was found between PCCE-2 and conventional colonoscopy for the assessment of mucosal disease activity. Moreover, PCCE-2 was better tolerated than colonoscopy in these patients.
20 pts with active ileocolonic Crohn’s disease undergoing capsule endoscopy using the second generation Pillcam capsule (PCCE 2) instead of a colonoscopy before and 8-12 weeks after treatment initiation with Infliximab or Adalimumab

Doel van het onderzoek

The goals of treatment in Crohn’s disease have evolved in recent years from symptom control to healing of mucosal lesions, usually visualized by endoscopy. Potent therapeutic agents, such as anti-TNF agents, have made restoration of mucosal integrity attainable in a significant proportion of patients. Moreover, anti-TNF therapy was shown to be more effective in patients that had visible ulcers on endoscopy than in patients without such lesions. This means that clinicians are recommended to check for the presence of ulcers before they embark on biological therapy. Finally, endoscopic evaluation of treatment effects in Crohn’s

disease has entered routine practice.

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Onderzoeksopzet

Before and 8-12 weeks after the start of treatment with anti-TNF agents

Onderzoeksproduct en/of interventie

20 patients with symptoms of active (ileo)colonic Crohn’s disease and biochemical evidence of active inflammation (reflected by elevated faecal calprotectin (> 250 ug/g) and/or increased CRP serum levels (i.e. > 5 mg/l)) that need an endoscopic evaluation before starting anti-TNF treatment (Infliximab or Adalimumab) will be invited to take part in this study. Patients will undergo capsule endoscopy using PCCE 2 instead of colonoscopy before starting anti-TNF. After 8-12 weeks of treatment the PCCE-2 procedure will be repeated.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Active ileocolonic Crohn’s disease with CDAI > 150 points

- Elevated faecal calprotectin >250 ug/g and/or increased CRP levels (> 5 mg/l)

- Colon imaging clinically indicated in order to determine disease activity before embarking on anti-TNF treatment

- Prior documentation of colonic involvement by Crohn’s disease in at least two colonic segments and documentation of colonic ulcers

- Ability to give informed consent and willing to undergo 2 Pillcam examination within 4 months

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Any contraindication for colon capsule examination including swallowing disorders, severe congestive heart failure, renal insufficiency, or co-morbities contraindicating these procedures.

- More than 1 bowel resection for CD

- Previous subtotal or total colectomy

- Active (draining) fistulas

- Proximal small bowel disease

- Known small bowel strictures

- High suspicion of small bowel strictures or colonic strictures.
In case of low suspicion of small bowel strictures patients have to undergo a test with the Agile patency capsule approximately 1 week prior to participation in the current study

- Short bowel or all stoma

- Need for MRI before capsule excretion

- Pacemaker or ICD

- Current pregnancy

- Current participation in an experimental clinical study

- Age younger than 18 years

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	16-06-2016
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-10-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50462
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5585
NTR-old	NTR6177
CCMO	NL55599.018.16
OMON	NL-OMON50462

Resultaten