Observationele studie naar de rol van α4β7 en andere afweercellen in pouchitis

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Lymhocyte homing plays a role in the pathofysiology of pouchitis and vedolizumab could be a therapeutic target.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24429

Bron
Nationaal Trial Register

Verkorte titel
n/a

Aandoening

Pouchitis, pouch, IPAA, Ileal pouch anal anastomosis.

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: Takeda

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Semi-quantitative analysis of α4β7+ T-lymphocytes in ileal pouch biopsies of

chronic pouchitis patients and changes thereof after resolution of endoscopic inflammation.

Toelichting onderzoek

Achtergrond van het onderzoek

Because of medically refractory disease or colorectal neoplasia development, about 15% of ulcerative colitis (UC) patients will need a proctocolectomy with ileal-anal pouch reconstruction (IPAA). A common complication of IPAA is pouchitis, a nonspecific inflammation of the pouch, which occurs in about 50% of UC patients with IPAA. The pathogenesis of pouchitis is not well understood, but the innate and adaptive immune responses, microbiota-host interactions or defects in intestinal epithelial cells may play a role in this. Vedolizumab, a humanized monoclonal antibody that specifically binds to the lymphocyte integrin α4β7 may be beneficial for the treatment of pouchitis. However, blocking the interaction between MAdCAM-1 and α4β7 integrin on memory T and B cells by vedolizumab, which has been shown to be beneficial in IBD, hasn’t been studied in pouchitis yet. With this observational study, we will look into different key players of lymphocyte trafficking in pouch biopsies of patients with and without pouchitis. We will also look at changes after treatment with vedolizumab.

Doel van het onderzoek

Lymhocyte homing plays a role in the pathofysiology of pouchitis and vedolizumab could be a therapeutic target.

Onderzoeksopzet

Group 1 and 2: 1 endoscopy

Group 3: 2 subsequent endoscopies, 1 year in between

Onderzoeksproduct en/of interventie

Group 1 and 2:

Day of endoscopy (scheduled in regular care):

- PDAI questionnaire

- Fecal sample

- 9ml Heparin tube

During endoscopy:

- 6 biopsies

Group 3:

Day of endoscopy (scheduled for EARNEST trial):

- PDAI questionnaire

- Fecal sample

- 9ml Heparin tube

During endoscopy:

- 6 biopsies

Additional endoscopy after 1 year (scheduled for EARNEST trial):

Day of endoscopy:

- PDAI questionnaire

- 5ml serum tube

- 9ml Heparin tube

During endoscopy:

- 6 biopsies

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Group 1:

- The subject has a history of ileal pouch anal anastomosis (IPAA) for Ulcerative Colitis completed at least 3 months prior to screening.

- The patient is scheduled for a surveillance or diagnostic endoscopy of the pouch.

- Age from 18 years, either male or female.

- Ability to give informed consent.

Group 2 and 3:

- The subject has a history of ileal pouch anal anastomosis (IPAA) for Ulcerative Colitis completed at least 3 months prior to screening.

- Age from 18 years, either male or female.

- Ability to give informed consent.

- The subject has chronic or recurrent pouchitis and may have antibiotic-dependent or antibiotic-refractory chronic pouchitis.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Group 1:

- The subject has an IPAA that is less than 3 months old.

- The subject has a history of a perforation of the intestine after endoscopy or surgery.

- The subject currently has acute or chronic pouchitis, or had pouchitis in the past 3 months.

- The subject had prior exposure to vedolizumab, natalizumab, rituximab, etrolizumab or anti-MAdCAM-1 therapy in the past 6 months.

- Inability to give informed consent.

- The patient has Crohn’s disease.

Group 2 and 3:

- The subject has an IPAA that is less than 3 months old.

- The subject currently uses or has prior exposure to vedolizumab, natalizumab, rituximab, etrolizumab or anti-MAdCAM-1 therapy in the past 6 months.

- The subject has a history of a perforation of the intestine after endoscopy or surgery.

- Inability to give informed consent.

- The patient has Crohn’s disease.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-03-2017
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-05-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49464
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6303
NTR-old	NTR6478
CCMO	NL60196.018.16
OMON	NL-OMON49464

Resultaten