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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24429

Source
Nationaal Trial Register

Brief title
n/a

Health condition

Pouchitis, pouch, IPAA, Ileal pouch anal anastomosis.

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Semi-quantitative analysis of α4β7+ T-lymphocytes in ileal pouch biopsies of chronic pouchitis patients and changes thereof after resolution of endoscopic inflammation.

Secondary outcome

1. Semi-quantitative analysis of key-players of lymphocyte trafficking in pouchitis (e.g. MAdCAM-1, CCR9, CCR10, CCL25, CCL28, αEβ7)

2. Changes of lymphocyte subsets after treatment with vedolizumab

3. Vedolizumab serum levels in peripheral blood of patients treated with vedolizumab

Study description

Background summary

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.

Study objective

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

Study design

Group 1 and 2: 1 endoscopy

Group 3: 2 subsequent endoscopies, 1 year in between

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-03-2017
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-05-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49464
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results