Expressie van CCL25 en CCR9 bij inflammatoire darmziekten en primaire scleroserende cholangitis.

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Primary sclerosing cholangitis (PSC) is a rare chronic cholestatic disease of unknown cause. Chronic inflammation leads to bile duct destruction resulting in liver failure. PSC is regarded as an immune dysbalance disease. PSC has a strong...

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

Samenvatting

ID

NL-OMON26243

Bron
NTR

Verkorte titel
PSColon

Aandoening

primary sclerosing cholangitis
inflammatory bowel disease
ulcerative colitis
Crohn's disease

primaire scleroserende cholangitis
inflammatoire darmziekten
colitis ulcerosa
ziekte van Crohn

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Expression of CCL25 in human colon.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Primary sclerosing cholangitis (PSC) is a rare chronic cholestatic disease of unknown cause. Chronic inflammation leads to bile duct destruction resulting in liver failure. PSC is regarded as an immune dysbalance disease. PSC has a strong association with IBD, especially ulcerative colitis and some consider PSC as an extraintestinal manifestation of IBD. The gut-homing lymphocyte paradigm offers a plausible explanation linking the gut and liver in PSC.

Primary objective:

To demonstrate and compare expression of CCL25 and CCR9+ lymphocytes in peripheral blood and colon of PSC-, PSC/IBD-, IBD-, gastroenteritis patients and controls.

Study design:

Exploratory case control study.

Study population:

1. Newly diagnosed PSC patients screened for IBD, ≥18 yr old;

2. a. Newly diagnosed UC patients, ≥18 yr old;

2. b. Infectious enterocolitis patients (bacterial/viral/parasitic), ≥18 yr old;

3. PSC/UC surveillance patients, ≥18 yr old;

4. UC surveillance patients, ≥18 yr old;

5. Controls referred for CRC screening, ≥18 yr old.

Main study parameters/endpoints:

1. Expression of CCL25 in human colon by immunohistochemistry;

2. Difference in proportion of CCL25 and/or CCR9+ lymphocytes in double stained colonic biopsies between patients and controls;

3. Quantitative analyses of CCL25 mRNA expression in colon of patients and controls;

4. Quantitative analyses α4β7/CCR9+ T cells in peripheral blood.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Colonic biopsies are obtained during surveillance colonoscopy at the Department of Gastroenterology and Hepatology AMC. 8 specimens at 3 levels, 24 specimens in total per patient. During standard surveillance colonoscopy procedure 32 biopsies are obtained for pathological analyses. The additive burden consists of 24 additional biopsies. One extra blood sample is drawn prior to colonoscopy.

Doel van het onderzoek

Primary sclerosing cholangitis (PSC) is a rare chronic cholestatic disease of unknown cause. Chronic inflammation leads to bile duct destruction resulting in liver failure. PSC is regarded as an immune dysbalance disease. PSC has a strong association with IBD, especially

ulcerative colitis and some consider PSC as an extraintestinal manifestation of IBD. The gut-homing lymphocyte paradigm offers a plausible explanation linking the gut and liver in PSC.

Onderzoeksopzet

One timepoint: PBMC isolation and biopsy collection during colonoscopy.

Onderzoeksproduct en/of interventie

Ileal and colonic biopsies during colonoscopy.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Newly diagnosed PSC patients screened for IBD, ≥18 yr old;

2. a. Newly diagnosed UC patients, ≥18 yr old;

2. b. Infectious enterocolitis patients (bacterial/viral/parasitic), ≥18 yr old;

3. PSC/UC surveillance patients, ≥18 yr old;

4. UC surveillance patients, ≥18 yr old;

5. Controls referred for CRC screening, ≥18 yr old.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Inability to give informed consent;

2. Bleeding diathesis.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2009
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-04-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2713
NTR-old	NTR2851
Ander register	METC AMC : MEC 09/059
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A