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

No registrations found.

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

Summary

ID

NL-OMON26243

Source
NTR

Brief title
PSColon

Health condition

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

primaire scleroserende cholangitis
inflammatoire darmziekten
colitis ulcerosa
ziekte van Crohn

Sponsors and support

Primary sponsor: C.IJ. Ponsioen, MD PhD
Dept. Gastroenterology and Hepatology Academic Medical Center Amsterdam
PO Box 22660
1100 DD Amsterdam
The Netherlands

c.y.ponsioen@amc.uva.nl
Source(s) of monetary or material Support: C.IJ. Ponsioen, MD PhD
Dept. Gastroenterology and Hepatology Academic Medical Center Amsterdam
PO Box 22660
1100 DD Amsterdam
The Netherlands

c.y.ponsioen@amc.uva.nl

Intervention

Outcome measures

Primary outcome

Expression of CCL25 in human colon.

Secondary outcome

1. Semiquantitative analyses of CCL25 and/or CCR9+ lymphocytes in double stained colonic biopsies between patients and controls;

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

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

Study description

Background summary

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.

Study objective

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.

Study design

One timepoint: PBMC isolation and biopsy collection during colonoscopy.

Intervention

Ileal and colonic biopsies during colonoscopy.

Contacts

Public
PO Box 22660
K. Boonstra
Dept. Gastroenterology and Hepatology
Room C2-231
Academic Medical Center Amsterdam
Amsterdam 1100 DD
The Netherlands
Scientific
PO Box 22660
K. Boonstra
Dept. Gastroenterology and Hepatology
Room C2-231
Academic Medical Center Amsterdam
Amsterdam 1100 DD
The Netherlands

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

1. Inability to give informed consent;

2. Bleeding diathesis.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2009
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-04-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results

Summary results
N/A