Role of connective tissue growth factor in peritoneal fibrosis and encapsulating peritoneal sclerosis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peritoneal and retroperitoneal conditions
Study type	Observational invasive

Summary

ID

NL-OMON32262

Source
ToetsingOnline

Brief title
CTGF in peritoneal fibrosis

Condition

- Peritoneal and retroperitoneal conditions
- Renal disorders (excl nephropathies)

Synonym
encapsulating peritoneal sclerosis, peritoneal fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Connective tissue growth factor, Encapsulating peritoneal sclerosis, Peritoneal dialysis, Peritoneal fibrosis

Outcome measures

Primary outcome

The main study parameters are thickness of the peritoneal submesothelial

compact zone, CTGF mRNA and protein expression in the peritoneum, and CTGF

levels in plasma, urine, and peritoneal effluent.

Secondary outcome

The secondary study parameters are the degree of vasculopathy in the

peritoneum, TGF-β1 and VEGF mRNA and protein expression in the peritoneum, and

TGF-β1 and VEGF levels in plasma, urine, and peritoneal effluent.

Study description

Background summary

Chronic treatment with peritoneal dialysis (PD) leads to alterations in the structure of the peritoneal membrane (peritoneal fibrosis). A severe form of peritoneal fibrosis is encapsulating peritoneal sclerosis (EPS) which has a high mortality rate. Transforming growth factor β1 (TGF-β1) plays a central role in peritoneal fibrosis. However, TGF-β1 has several other useful functions. Therefore, direct inhibition of general TGF-β1 activity is not an attractive therapeutic option and it remains important to explore the role of additional growth factors.

Study objective

Our primary objective is to investigate the role of connective tissue growth factor (CTGF, a downstream mediator of profibrotic TGF-β1 activity) in peritoneal fibrosis and EPS. We hypothesize that soluble levels of CTGF and CTGF expression in the peritoneum correlate with the degree and severity of peritoneal fibrosis.

Study design

Cross-sectional.

Study burden and risks

For this study we need one extra blood collection, urine collection, and a biopsy of the parietal peritoneum, which will be obtained during the operation. In patients who are treated by PD a peritoneal equilibration test will be performed. All procedures will be done during the admission for the kidney transplantation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with ESRD who are about to undergo a kidney transplantation in the University Medical Centre Utrecht.

Exclusion criteria

Patients who are unable to give informed consent.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-10-2008
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO

Date:	02-09-2008
Application type:	First submission
Review commission:	METC NedMec

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
CCMO	NL23556.041.08