Encapsulating peritoneal sclerosis after kidney transplantation in patients previously treated by peritoneal dialysis: a prospective observational study.

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Our primary objective is to determine the incidence of EPS after kidney transplantation in patients previously treated by PD. We hypothesize that there is an increasing incidence of symptomatic and asymptomatic EPS after kidney transplantation.

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

Summary

ID

NL-OMON40061

Source
ToetsingOnline

Brief title
EPS after kidney transplantation.

Condition

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

Synonym
encapsulating peritoneal sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Baxter ,Een deel van het onderzoek wordt gefinancieerd door Baxter;leverancier van peritoneaal dialyse materialen.

Intervention

Keyword: Encapsulating peritoneal sclerosis, Kidney transplantation, Peritoneal dialysis, Peritonitis

Outcome measures

Primary outcome

The incidence of EPS, both clinically evident and silent, after kidney

transplantation in patients previously treated by PD.

Secondary outcome

Thickness of the submesothelial compact zone (in µm).

Thickness of the peritoneum assessed by ultrasound (in µm).

Study description

Background summary

Encapsulating peritoneal sclerosis (EPS) is a serious complication in patients on peritoneal dialysis (PD). Diffuse peritoneal sclerosis leads to encasement of the small bowel. Clinical features of EPS including recurrent abdominal pain, nausea, vomiting, anorexia, bowel obstruction and severe weight loss. Total parenteral nutrition is often needed and in severe cases surgical treatment is indicated. Mortality rate is high because of malnutrition, infections, and surgical complications. The diagnosis of EPS is difficult and mainly based on clinical signs and symptoms. Radiological investigations play a significant role in confirming a suspected diagnosis of EPS. Recently, a remarkable increase in EPS cases was observed, especially EPS manifesting in the first year after kidney transplantation. However, the exact incidence of post-transplant EPS in PD patients and its risk factors are unknown and have not been studied prospectively.

Study objective

Our primary objective is to determine the incidence of EPS after kidney transplantation in patients previously treated by PD. We hypothesize that there is an increasing incidence of symptomatic and asymptomatic EPS after kidney transplantation.

Study design

Prospective, observational study.

Study burden and risks

To make the diagnosis we will use a questionnaire, blood test, abdominal ultrasound, and abdominal computed tomography. These investigations will be performed at baseline, and after 6 and 18 months. Before kidney transplantation a peritoneal equilibration test will be performed. During kidney transplantation procedure, a biopsy of the parietal peritoneum will be obtained in 20 patients.

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 treated by PD and are about to undergo a kidney transplantation in the University Medical Center 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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-08-2009
Enrollment:	54
Type:	Actual

Ethics review

Approved WMO

Date:	14-07-2009

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-10-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL26650.041.09