

# 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.

<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Peritoneal and retroperitoneal conditions
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON32530

### Source

ToetsingOnline

### Brief title

EPS after kidney transplantation.

### Condition

- Peritoneal and retroperitoneal conditions
- Renal disorders (excl nephropathies)
- Renal and urinary tract therapeutic procedures

### Synonym

encapsulating peritoneal sclerosis

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Baxter, Er is financiële ondersteuning aangevraagd bij 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

Factors predisposing to EPS in patients after kidney transplantation.

## 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.

## **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: Will not start

Enrollment: 60

Type: Anticipated

# Ethics review

Not approved

Date: 02-12-2008

Application type: First submission

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	NL24646.041.08