# Randomised controlled study of 'physiological' peritoneal dialysis solutions

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
28/09/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
28/09/2007	Completed	Results
Last Edited	Condition category	Individual participant data
29/03/2018	Urological and Genital Diseases	Record updated in last year

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr S Fan

#### Contact details

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# Additional identifiers

# Protocol serial number

N0205182207

# Study information

#### Scientific Title

Randomised controlled study of 'physiological' peritoneal dialysis solutions

### **Study objectives**

We propose conducting a randomised controlled study of new patients commencing peritoneal dialysis. We shall compare patients who start on 'physiological' (bicarbonate-based) versus 'standard' (lactacte-based) dialysate solution. We propose to study the effect of these solutions on mortality, duration of successful PD and peritonitis rates.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

#### Primary study design

Interventional

## Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Urological and Genital Diseases: Peritoneal dialysis

#### Interventions

"Physiological" (pH neutral) versus "standard" (low pH) dialysate solution

# Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome(s)

Patients using physiological solutions will have lower peritonitis rate than control group.

# Key secondary outcome(s))

- 1. Patients using physiological solutions will have better preservation of residual kidney function
- 2. Patients using physiological solutions will have smaller changes in peritoneal membrane function assessed by PET than control group
- 3. Patients using physiological solutions will have reduced composite end-point of mortality and PD failure defined by transfer to HD in patients using physiological solutions

# Completion date

29/04/2013

# **Eligibility**

# Key inclusion criteria

All patients selected to use a PD system that has physiological and standard solutions available

# Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

## Age group

**Not Specified** 

#### Sex

All

# Key exclusion criteria

- 1. Patients unable to provide informed consent
- 2. Patients where the use of a certain solution is indicated or contra-indicated for medical reasons (eg known allergy)

#### Date of first enrolment

29/01/2004

#### Date of final enrolment

29/04/2013

# Locations

#### Countries of recruitment

**United Kingdom** 

England

# Study participating centre

Department of Renal Medicine and Transplantation

London United Kingdom E1 1BB

# Sponsor information

## Organisation

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

# Funder(s)

# Funder type

Government

#### Funder Name

Barts and The London NHS Trust

#### Funder Name

NHS R&D Support Funding

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes