

Randomised controlled study of 'physiological' peritoneal dialysis solutions

Submission date 28/09/2007	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 28/09/2007	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 29/03/2018	Condition category Urological and Genital Diseases	☐ Individual participant data
		☐ 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
Department of Renal Medicine and Transplantation
The Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB
+44 0207 377 7367
s.fan@qmul.ac.uk

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' (lactate-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

Primary study design

Interventional

Study design

Randomised controlled trial

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