

Randomised controlled study of 'physiological' peritoneal dialysis solutions

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

29/01/2004

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

Age group

Not Specified

Sex

Both

Target number of participants

131

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

England

United Kingdom

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

Sponsor details

The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Barts and The London NHS Trust

Funder Name

NHS R&D Support Funding

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration