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Randomised controlled study of 'physiological' peritoneal dialysis solutions

Submission date	Recruitment status	[_] Prospectively registered
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

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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' (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

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