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Bioimpedance as a tool for fluid management in peritoneal dialysis patients

Submission date	Recruitment status	[_] Prospectively registered
29/11/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/12/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/01/2017	Urological and Genital Diseases	

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
NCT00801112

Secondary identifying numbers

N/A

Study information

Scientific Title
Developing bioimpedance as a tool for fluid management in peritoneal dialysis patients: a validation study

Study objectives
Regular monitoring of bioimpedance (BIA) adds value to the management of fluid status in peritoneal dialysis (PD) patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Staffordshire Local Research Ethics Committee - submission pending as of 29/11/2008

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
End stage renal disease on peritoneal dialysis

Interventions
Clinician to use whatever tools at their disposal to achieve dry weight in PD patients including restricted dietary salt and fluid intake, increased use of hypertonic PD solutions and modality change. BIA to track fluid status changes. BIA measurements will also be taken for the control group but the results will not be acted upon

BIA measurements for all patients will be taken at 3 months intervals. The total duration of the intervention is 1 year.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Extra-cellular fluid volume (ECFv) determined from BIA

Secondary outcome measures
Outcomes will be measured at 6-month intervals:
1. Blood pressure control (clinic)
2. Residual urine volume:
2.1. Development of anuria (<200 ml/day)
2.2. Time to halving of urine volume at randomisation
3. Membrane function:
3.1. Glucose exposure
3.2. Solute transport
3.3. Ultrafiltration (UF) capacity
3.4. Free water transport (limited centres, own resources)
4. Cardiac function:
4.1. Brain natriuretic peptide (BNP) (all centres)
4.2. Echocardiography (ECHO) (limited centres, own resources)
5. Fluid status using gold standard methods (limited centres, own resources)

Overall study start date
15/01/2009

Completion date
15/11/2011

Eligibility

Key inclusion criteria
1. All PD patients who are clinically stable
2. Age >16 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria

1. Patients planning discontinuation of PD within 6 months
2. Patients who are unable to give consent
3. Patients who have peritonitis the last 30 days prior to study enrollment
4. Patients who are pregnant

Date of first enrolment
15/01/2009

Date of final enrolment
15/11/2011

Locations

Countries of recruitment
England

Italy

Netherlands

Spain

Sweden

United Kingdom

Study participating centre
University Hospital of North Staffordshire
Stoke on Trent
United Kingdom
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Sponsor information

Organisation
University Hospital of North Staffordshire (UK)

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Sponsor type
Government

Website
http://www.uhns.nhs.uk

Funder(s)

Funder type
Industry

Funder Name
Baxter (UK) - Clinical Evidence Council

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2016		Yes	No