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Dialysate magnesium - a novel tool to abrogate dialysis-induced myocardial stunning?

Submission date 28/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/11/2010	**Overall study status** Completed	
Last Edited 09/09/2016	**Condition category** Surgery	

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
RD-5103-013-07

Study information

Scientific Title
A randomised controlled cross-over trial of 0.5 mmol/L versus 1.0 mmol/L dialysate magnesium to abrogate dialysis-induced myocardial stunning

Study objectives
Increasing dialysate magnesium will abrogate dialysis-induced myocardial stunning.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Trent Research Ethics Committee, 04/09/2008, ref: 08/H0405/42

Study design
Randomised controlled cross-over 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Dialysis-induced myocardial stunning

Interventions
Each patient undergoes one week (three dialysis treatments) of standard haemodialysis, and one week (three dialysis treatments) of standard haemodialysis with supplemental oxygen to breathe; the chronological order of the two weeks is allocated by randomisation. Patients thereby act as their own controls. Monitored visits occur on the third treatment of each week. There is no further follow-up.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dialysate magnesium

Primary outcome measure
Development of regional wall motion abnormalities.
Key observations are taken pre-dialysis (baseline), 15 minutes prior to end of dialysis (peak stress) by cardiac echocardiography (for later offline semi-automated analysis for regional wall motion abnormalities).

Secondary outcome measures
Haemodynamic variables observed pre-dialysis, and throughout dialysis treatment, with continuous non-invasive measurement by finometer, and NICOM (bioreactance).

Overall study start date
01/06/2008

Completion date
01/11/2009

Eligibility

Key inclusion criteria
1. Over 18 years old, either sex
2. Chronic haemodialysis greater than 3 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. New York Heart Association (NYHA) grade IV heart failure
2. Cardiac transplant
3. Known disorder of magnesium metabolism
4. Magnesium supplementation
5. Recent arrhythmia

Date of first enrolment
01/06/2008

Date of final enrolment
01/11/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Renal Medicine
Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation
Derby Hospitals NHS Foundation Trust (UK)

Sponsor details
Royal Derby Hospital
Uttoxeter Road
Derby
England
United Kingdom
DE22 3NE

Sponsor type
Hospital/treatment centre

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

Funder(s)

Funder type
Charity

Funder Name
Kidney Research UK (UK) (ref: RP5/2008)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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