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

Submission date
28/05/2010

Registration date
04/11/2010

Last Edited
09/09/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

[_] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[_] Results

[_] Individual participant data

[_] 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
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