

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

Submission date 28/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/11/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 09/09/2016	Condition category Surgery	<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

Contact name
Dr Helen Jefferies

Contact details
Department of Renal Medicine
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

Study participating centre

Department of Renal Medicine

Derby

United Kingdom

DE22 3NE

Sponsor information

Organisation

Derby Hospitals NHS Foundation Trust (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

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary