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Study to compare the effects of cooled dialysis fluid with a normal temperature of dialysis fluid on the pumping function of the heart

Submission date	Recruitment status	[_] Prospectively registered
12/09/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/10/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/10/2018	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

Protocol serial number
DHRD/2009/031

Study information

Scientific Title

The effects of cooling the dialysate on systolic dysfunction in chronic haemodialysis patients: a multicentre randomised controlled trial

Study objectives
This study will examine whether cooling the dialysate retards the development of cardiac systolic dysfunction in haemodialysis patients. This study will also examine whether cooling the dialysate will have an abrogating effect on a wide range of haemodynamic functional measures and microvascular function.

Primary objective: To observe the effects of cooling the dialysate on cardiac systolic function after 12 months using magnetic resonance imaging.

The secondary aims of the study are to observe the effects of cooling the dialysate on:
1. Left ventricular ejection fraction measured with intra-dialytic echocardiography
2. Frequency and severity of myocardial stunning measured with intra-dialytic echocardiography
3. A range of measures of haemodynamic variables, including cardiac output, pulse rate, heart rate, arrhythmias and frequency of intradialytic hypotension
4. Microvascular function using myography
5. Cross-sectional correlants of cardiovascular outcomes to biomarkers

Please note, as of 26/04/2011 the anticipated end date for this trial has been extended from 17 /09/2012 to 17/12/2012 and the target number of participants reduced from 198 to 106.

As of 02/02/2012, the target number of participants have been reduced from 106 to 102.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Research Ethics Committee, approved on 30/6/2009 (ref: 09/H0408/71)

Primary study design
Interventional

Study design
Multicentre randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic kidney disease

Interventions
Current interventions as of 26/04/2012

Individualised cooled dialysate vs dialysate at 37 degrees centigrade (control).

Duration of interventions: 12 months

Previous interventions
Individualised cooled dialysate vs dialysate at 37 degrees centigrade (control).

Duration of interventions: 18 months (Note: primary endpoint is measured at 12 months).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Resting left ventricular ejection fraction on cardiac magnetic resonance imaging at 12 months.

Key secondary outcome(s)
Current secondary outcome measure(s) as of 26/04/2012
1. Left ventricular ejection fraction measured by intra-dialytic echocardiography
2. Frequency and severity of myocardial stunning measured with intra-dialytic echocardiography
3. A range of haemodynamic variables, including cardiac output, pulse rate, heart rate, arrhythmias and frequency of intra-dialytic hypotension
4. Endothelial function using myography
5. A range of biochemical markers of cardiac and endothelial function

All secondary outcomes will be assessed at baseline and 12 months

Previous secondary outcome measure(s)
1. Left ventricular ejection fraction measured by intra-dialytic echocardiography
2. Frequency and severity of myocardial stunning measured with intra-dialytic echocardiography
3. A range of haemodynamic variables, including cardiac output, pulse rate, heart rate, arrhythmias and frequency of intra-dialytic hypotension
4. Endothelial function using myography
5. A range of biochemical markers of cardiac and endothelial function

All secondary outcomes will be assessed at 6, 12 and 18 months

Completion date
17/12/2012

Eligibility

Key inclusion criteria
1. Male and female, age >=16 years old
2. Patients having haemodialysis treatment at least 3 times per week
3. Willing and able to provide consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Current exclusion criteria as of 26/04/2012
1. Exposure to haemodialysis >180 days
2. Contraindications for using magnetic resonance imaging (MRI) (e.g. patients with pacemakers and metal implants)
3. Inability to tolerate MRI due to claustrophobia
4. New York Heart Association grade IV heart failure
5. Mental incapacity to consent
6. Pregnancy or lactating patients

Previous exclusion criteria as of 02/02/2012
1. Exposure to haemodialysis >180 days
2. Contraindications for using magnetic resonance imaging (MRI) (e.g. patients with pacemakers and metal implants)
3. Inability to tolerate MRI due to claustrophobia
4. New York Heart Association grade IV heart failure
5. Mental incapacity to consent

Previous exclusion criteria as of 26/04/2011:
1. Exposure to haemodialysis >180 days
2. Contraindications for using magnetic resonance imaging (MRI) (e.g. patients with pacemakers and metal implants)
3. Inability to tolerate MRI due to claustrophobia
4. New York Heart Association grade IV heart failure
5. Cardiac transplant recipients
6. Mental incapacity to consent

Previous exclusion criteria:
1. Exposure to haemodialysis for >90 days
(criteria 2 - 6 remained unchanged)

Date of first enrolment
17/09/2009

Date of final enrolment
17/12/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Derby Hospital
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Sponsor information

Organisation
Derby Hospitals NHS Foundation Trust (UK)

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-0408-16195)

Results and Publications

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	07/08/2015		Yes	No
Protocol article	study protocol	21/06/2012		Yes	No