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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 12/09/2009	**Recruitment status** No longer recruiting
Registration date 15/10/2009	**Overall study status** Completed
Last Edited 26/10/2018	**Condition category** Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
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)

Study design
Multicentre randomised controlled 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
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 measure
Resting left ventricular ejection fraction on cardiac magnetic resonance imaging at 12 months.

Secondary outcome measures
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

Overall study start date
17/09/2009

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

Age group
Adult

Sex
Both

Target number of participants
102 (198 at time of registration)

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
England

United Kingdom

Study participating centre
Royal Derby Hospital
DERBY
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DE22 3NE

Sponsor information

Organisation
Derby Hospitals NHS Foundation Trust (UK)

Sponsor details
Research and Development Department
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Sponsor type
Hospital/treatment centre

Website
http://www.derbyhospitals.nhs.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

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