

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

<b>Submission date</b> 12/09/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/10/2009	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 26/10/2018	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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  $\geq 16$  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

United Kingdom

DE22 3NE

## **Sponsor information**

**Organisation**

Derby Hospitals NHS Foundation Trust (UK)

**Sponsor details**

Research and Development Department

Derby Hospitals NHS Foundation Trust

Royal Derby Hospital

Uttoxeter Road

Derby

England

United Kingdom

DE22 3DT

**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?
<a href="#">Protocol article</a>	study protocol	21/06/2012		Yes	No
<a href="#">Results article</a>	results	07/08/2015		Yes	No