

Effect of reduced temperature haemodialysis on myocardial function

Submission date 09/07/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/08/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 02/09/2020	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Patients with kidney failure who need haemodialysis (filtering the blood to get rid of waste products) three a week are at higher risk of death due to heart attacks or abnormal heart rhythms. This can alter the size and shape of their hearts. In addition, changes that occur during the haemodialysis therapy, such as fall in blood pressure, are associated with a poorer outcome. This could be due to a poor blood supply to the heart. These falls in blood pressure can be improved by reducing the temperature of the blood during dialysis. The trialists have shown that in patients requiring dialysis, heart muscle cells react in a different way even when they appear to be working well. They would like to further explain the short term effects of dialysis on heart function by studying the changes in biochemical parameters (high-energy phosphates) which can be measured using magnetic resonance imaging. They would like find out the relationship between blood pressure variation at the time of haemodialysis and changes in these biochemical parameters.

Who can participate?

Adult patients who are receiving haemodialysis

What does the study involve?

Participants are randomly allocated to one to two groups: one group undergoes magnetic resonance scanning immediately before haemodialysis and when the blood is at the normal temperature (37C) and the other group undergoes the scanning at a reduced temperature (35C).

What are the possible benefits and risks of participating?

Patients may experience a reduction in HEPs and thereby benefit from better control of blood pressure during dialysis and cold dialysis. There are no risks associated with reduced temperature dialysis or MRI scanning.

Where is the study run from?

NHS Greater Glasgow and Clyde (UK)

When is the study starting and how long is it expected to run for?

August 2014 to August 2015

Who is funding the study?
Academy of Medical Sciences (UK)

Who is the main contact?
Dr Rajan Patel
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
126372

Protocol serial number
1.0, IRAS 126372

Study information

Scientific Title
Effect of cool temperature haemodialysis on myocardial metabolic function

Study objectives
The trialists wish to further evaluate the effects of cold intermittent haemodialysis on myocardial contractile and metabolic activity measured by MRI. They propose to perform a crossover interventional study investigating the effect cold dialysis on myocardial function and high-energy phosphate (HEP) levels. They will correlate these data with intradialytic blood pressure changes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland REC, 16/07/2013, ref. 13/WS/0175

Study design

Crossover interventional study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

End stage renal failure

Interventions

Cardiac magnetic resonance (CMR) and magnetic resonance scanning (MRS) on two different groups (randomly allocated) of maintenance haemodialysis patients:

Group 1: Immediately before and after normal temperature (37°C) haemodialysis.

Group 2: Reduced temperature (35C) haemodialysis.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Changes in PCr: ATP and correlation of these changes with intradialytic blood pressure variation

2. Effect of cold dialysis on these measurements

These will be measured at 3, 6 and 12 months

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/08/2015

Eligibility**Key inclusion criteria**

All patients aged over 18 years old receiving maintenance haemodialysis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/08/2014

Date of final enrolment

01/08/2015

Locations**Countries of recruitment**

United Kingdom

Scotland

Study participating centre**University of Glasgow**

Glasgow

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G12 8TA

Sponsor information**Organisation**

Academy of Medical Sciences (UK)

ROR

<https://ror.org/00c489v88>

Funder(s)**Funder type**

Research organisation

Funder Name

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?
HRA research summary			28/06/2023	No	No