ISRCTN63390185 https://doi.org/10.1186/ISRCTN63390185

Effect of reduced temperature haemodialysis on myocardial function

Submission date	Recruitment status	[_] Prospectively registered
09/07/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/08/2014	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/09/2020	Urological and Genital Diseases	[_] 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
rajan.patel@glasgow.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Rajan Patel

Contact details
126 University Place
Glasgow
United Kingdom
G12 8TA
-
rajan.patel@glasgow.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number
126372

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2014

Completion date

01/08/2015

Eligibility

Key inclusion criteria
All patients aged over 18 years old receving maintenance haemodialysis

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

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
Scotland

United Kingdom

Study participating centre
University of Glasgow
Glasgow
United Kingdom
G12 8TA

Sponsor information

Organisation
Academy of Medical Sciences (UK)

Sponsor details
41 Portland Place
London
United Kingdom
W1B 1QH
-
info@acmedsci.ac.uk

Sponsor type
Research organisation

ROR
https://ror.org/00c489v88

Funder(s)

Funder type
Research organisation

Funder Name
Academy of Medical Sciences (UK) - Starter Grants for Clinical Lecturers

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?
HRA research summary			28/06/2023	No	No