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Study to investigate changes in blood pressure with different types of kidney dialysis treatments

Submission date	Recruitment status	[X] Prospectively registered
26/03/2019	Stopped	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/03/2019	Stopped	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/07/2022	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Haemodialysis has been the standard treatment for patients with chronic kidney disease for more than 50 years, with almost 3 million patients treated worldwide. Despite advances in dialysis technology, the 5-year survival for patients treated by haemodialysis is much less than that of some common cancers; with heart disease being he commonest cause of death. Blood pressure is typically high before a dialysis session, and then falls as fluid is removed from patients during the dialysis session. Low blood pressure (hypotension) is the commonest complication of routine outpatient haemodialysis treatments, estimated to occur in 20-40% of all treatments. Hypotension during haemodialysis is associated with an increased risk of both mortality and also for the older patient an increased risk of developing frailty and need for help in looking after themselves. Haemodiafiltration (HDF) is a type of haemodialysis but increases the range of substances compared to haemodialysis (HD). Some studies have suggested that HDF treatments have a lower risk of hypotension, and reduce mortality from any cause, and in particular mortality from heart disease. The aim of this study is to determine whether there are differences in blood pressure and stiffness of arteries in patients treated by HDF compared to HD.

Who can participate?
This study is only open to patients already taking part in the United Kingdom High-flux Haemodialysis vs High-volume Haemodiafiltration Registry Trial (H4RT)

What does the study involve?
Apart from taking part in the H4RT, patients are asked to attend for two echocardiograms in 2 years, additional blood tests during three dialysis sessions in 2 years, wearing an ambulatory blood pressure machine three times in 2 years, having three bioimpedance measurements in 2 years, and completing a simple test of cognitive function (the same one which is used on the president of the USA as part of their annual health check) three times in 2 years.

What are the possible benefits and risks of participating?
As with many studies there is no immediate benefit, but the results of the study will help

determine whether one type of kidney dialysis treatment is better than the other, and also potentially provide information about targets for blood pressure control for kidney dialysis patients. No additional risks are expected over and above attending for dialysis, as all tests are established in routine clinical practice.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
January 2017 to March 2022

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Prof. Andrew Davenport
andrewdavenport@nhs.net

Contact information

Type(s)
Scientific

Contact name
Prof Andrew Davenport

ORCID ID
http://orcid.org/0000-0002-4467-6833

Contact details
UCL Department of Nephrology
London
United Kingdom
NW3 2QG
+44 (0)2077940500
andrewdavenport@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1.1

Study information

Scientific Title
Study To Investigate The Change In Hypotensive Episodes during Dialysis (STITCHED)

Acronym
STITCHED

Study objectives
That treatment of patients with kidney failure with higher volume on-line haemodiafiltration leads to fewer episodes of intra-dialytic hypotension than conventional high-flux haemodialysis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/02/2019, East Midlands Leicester Central Research Ethics Committee (The Old Chapel
Royal Standard Place, Nottingham, NG1 6FS; Email: nrescommittee.eastmidlands-leicestercentral@nhs.net), REC ref: 18/EM/0212

Study design
Observational study nested within the UK H4RT trial

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format. For further information please contact trial manager n.irani@nhs.net

Health condition(s) or problem(s) studied
Kidney failure treated by haemodialysis

Interventions
Measured at study entry and at 24 months:
1. Ambulatory blood pressure and pulse wave velocity
2. Trans-thoracic echocardiography
3. Bioimpedance

4. Montreal Cognitive Assessment
5. Beta-2 microglobulin clearance
6. Measurement of cardiac biomarkers

Intervention Type
Other

Primary outcome measure
Intra-dialytic hypotensive episodes recorded quarterly

Secondary outcome measures
1. Ambulatory blood pressure measured at study entry, 12 months and completion at 24 months
2. Arterial stiffness measured using pulse wave velocity (pressure mmHg) at study entry, 12 months and completion at 24 months
3. Cognitive function assessed using Montreal cognitive assessment at study entry, 12 months and completion at 24 months
4. Extracellular water volumes measured using bioimpedance (volume L) at study entry, 12 months and completion at 24 months
5. Cardiac biomarkers measured using lab test at study entry, 12 months and completion at 24 months
6. Cardiac echocardiographic parameters and function measured using transthoracic echocardiogram at study entry and study completion at 24 months
7. Clearance of the middle molecule β2 microglobulin measured using lab test at study entry, 12 months and completion at 24 months

Overall study start date
31/01/2017

Completion date
31/03/2022

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
Patients randomised to The UK High-flux Haemodialysis vs High-volume Haemodiafiltration Registry Trial (H4RT) National Institute Health Research (NIHR) Health Technology Assessment 15/80/52

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
346

Key exclusion criteria
1. Not enrolled in H4RT study
2. Unable to provide informed consent

Date of first enrolment
15/04/2019

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
University College London

Sponsor details
Gower St
Bloomsbury
London
England
United Kingdom
WC1E 6BT
+44 (0)20 7679 2000
uclh.randd@nhs.net

Sponsor type
University/education

Website
https://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Main publication expected 2023

Intention to publish date
01/12/2023

Individual participant data (IPD) sharing plan
On completion the data will be stored in UCL (University College London) library archive in anonymised form. Study data will be retained for 15 years. Consent forms do not have a statement agreeing that data can be used by other researchers. As this is a sub-study of the United Kingdom High-flux Haemodialysis vs High-volume Haemodiafiltration Registry Trial (H4RT), then requests to access data once the trial has finished and main papers published will by application to the United Kingdom High-flux Haemodialysis vs High-volume Haemodiafiltration Registry Trial (H4RT).

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No