

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

Submission date 26/03/2019	Recruitment status Stopped	☒ Prospectively registered ☐ Protocol
Registration date 28/03/2019	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 11/07/2022	Condition category Urological and Genital Diseases	☐ Individual participant data ☐ 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 the 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
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Contact information

Type(s)
Scientific

Contact name
Prof Andrew Davenport

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)

Diagnostic

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(s)

Intra-dialytic hypotensive episodes recorded quarterly

Key secondary outcome(s)

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 $\beta 2$ microglobulin measured using lab test at study entry, 12 months and completion at 24 months

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Royal Free Hospital

Pond Street

London

United Kingdom

NW3 2QG

Sponsor information

Organisation

University College London

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

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 be 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes