

# A study comparing a form of haemodialysis that filters and replaces high volumes of blood water during each treatment (high-volume haemodiafiltration) with a form of haemodialysis that doesn't (high-flux haemodialysis)

<b>Submission date</b> 02/10/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 10/10/2017	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/12/2024	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English Summary

### Background and study aims

Most people with kidney failure need blood cleaning treatment (haemodialysis) for four hours three times a week up at a hospital/clinic. This is for the rest of their life unless they are fit to receive a kidney transplant. Survival and quality of life on haemodialysis are poor. The addition of filtration (the removal and replacement of fluid) to regular haemodialysis (which allows toxins to leave the blood with minimal fluid removal/ replacement) is known as haemodiafiltration. The aim of this study is to see whether removing and replacing 21 or more litres of fluid from the blood at the time of a standard dialysis treatment reduces death or hospitalisation from cardiac events or infections in people with kidney failure. Effects on quality of life, admission to hospital, symptoms, infection rates and costs are also examined.

### Who can participate?

Adults aged 18 and older who are receiving dialysis treatments three times a week.

### What does the study involve?

This study will randomly allocate patients already on dialysis in one of 20 centres in the UK are randomly allocated to switch to either haemodialysis or haemodiafiltration. This does not noticeably change the dialysis procedure as far as the patient is concerned – it is still 4 hours 3 times a week – it just requires changes in equipment and nurse practice. It does however require a greater volume of high-quality water. A research nurse collects the initial clinical information. All follow-up is carried out using data already routinely collected by the UK Renal Registry or by linking with other health care databases. Quality of life information is collected. Interviews are carried out and conversations studied in the preparatory and recruitment stages of the study.

What are the possible benefits and risks of participating?

Participants may benefit haemodiafiltration may improve survival as it may remove toxins more effectively, especially if high volumes are used (i.e. more than 21L of water removed and replaced per session. On the downside, such volumes of filtration could remove essential proteins or introduce toxins or infections from the water supply. Therefore it is needed to establish if haemodiafiltration results in benefits to patients, is safe and justifies any additional financial and environmental (e.g. water) costs.

Where is the study run from?

This study is being run by the University of Bristol (UK) and takes place in different hospitals in the UK.

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

May 2017 to September 2025 (updated 20/08/2021, previously: March 2024)

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

1. Dr Sunita Procter

H4rt-study@bristol.ac.uk

2. Prof Fergus Caskey

Fergus.caskey@bristol.ac.uk

### **Study website**

<http://www.bristol.ac.uk/population-health-sciences/projects/h4rt-trial/>

## **Contact information**

### **Type(s)**

Public

### **Contact name**

Dr Sunita Procter

### **ORCID ID**

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### **Contact details**

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### **Type(s)**

Scientific

**Contact name**

Prof Fergus Caskey

**ORCID ID**

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**Contact details**

Learning and Research

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

227067

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

CPMS 34704, IRAS 226067

## Study information

**Scientific Title**

The High-volume Haemodiafiltration vs High-flux Haemodialysis Registry Trial (H4RT)

**Acronym**

H4RT

**Study hypothesis**

The aim is to establish the effectiveness and cost-effectiveness of high-volume HDF compared with high-flux HD in adult patients with ESKD on maintenance thrice weekly in-centre HD. This will be done by running a randomised controlled trial using non-cancer mortality or hospital admission due to a cardiovascular event or infection as our primary outcome.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

**Study design**

Randomized; Interventional; Design type: Treatment, Device, Complex Intervention

**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

**Condition**

Renal failure

**Interventions**

Participants in the intervention arm receive in-centre, high-volume, post-dilution HDF typically for four hours, three times a week. Participants in the control arm receive in-centre high-flux HD typically for four hours, three times a week.

Participants in both arms are followed up for 32 months minimum (50 months maximum) using six monthly paper or electronic questionnaires. Follow up data are also accessed by linking to routine healthcare databases i.e. UK Renal Registry, Hospital Episode Statistics and Office for National Statistics data (and their equivalents in Wales, Scotland and Northern Ireland).

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Not provided at time of registration

**Primary outcome measure**

1. Non-cancer mortality or hospital admission with a cardiovascular event or infection from randomisation to end of follow-up
2. A composite of first of non-cancer mortality or admission to hospital related to a cardiovascular event or infection is measured using datasets (UKRR, Hospital Statistics & ONS) from randomisation to end of follow-up (32-50 months depending on recruitment)

**Secondary outcome measures**

1. All-cause mortality, cardiovascular and infection related morbidity and mortality. Health-related quality of life (QoL), cost effectiveness and environmental impact
2. All-cause mortality is measured using datasets (UKRR and ONS) from randomisation to end of follow-up (32-50 months depending on recruitment)
3. Cardiovascular – cause specific hospitalisation and mortality is measured using datasets ((UKRR, Hospital Statistics (HES, PEDW, ISD, NISRA) & ONS) from randomisation to end of follow-up (32-50 months depending on recruitment)
4. Infection – cause- specific hospitalisation and mortality using datasets (MRSA & MSSA) (Public Health England) from randomisation to end of follow-up (32-50 months depending on recruitment)
5. Health-related quality of life (QoL) – quality adjusted life years gained (EQ-5D-5L), generic quality of life (SF-36), disease specific (kidney symptoms within KDQOL-36) and time to recover after dialysis: From Patient Questionnaires - assessed using repeated measures taken six-monthly
6. Cost effectiveness and environmental impact (including locally purified water, manufactured saline and plastic consumables): using all available data for the full duration of follow-up (32-50 months)

**Overall study start date**

01/05/2017

**Overall study end date**

30/09/2025

## Eligibility

**Participant inclusion criteria**

1. Adult patients aged 18 and older receiving in-centre, maintenance HD or HDF for ESKD
2. Dialysing three times a week in a main dialysis unit or satellite unit
3. Potential to achieve high-volume HDF

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 1550; UK Sample Size: 1550

**Total final enrolment**

1553

**Participant exclusion criteria**

1. Lack of capacity to consent
2. Clinician predicted prognosis of less than 3 months
3. Started maintenance HD within the preceding 4 weeks
4. Transition to living kidney donor transplant or home dialysis scheduled within next 3 months
5. Not suitable for high-volume HDF for other clinical reasons such as dialysis less than thrice weekly or unlikely to achieve sufficient blood flow rates with current vascular access
6. Treatment with HDF for more than 3 months prior to inclusion in the trial or prior intolerance of HDF

**Recruitment start date**

01/11/2017

**Recruitment end date**

08/09/2022

## **Locations**

**Countries of recruitment**

England

Scotland

United Kingdom

**Study participating centre****Southmead Hospital**

North Bristol NHS Trust (Lead Centre)

Southmead Road

Westbury-On-Trym

Bristol

United Kingdom

BS10 5NB

**Study participating centre****Queens Medical Centre**

Nottingham University Hospitals NHS Trust

Trust Headquarters

Derby Road

Nottinghamshire

Nottingham

United Kingdom

NG7 2UH

**Study participating centre**

**Ipswich Hospital NHS Trust**  
Heath Road  
Ipswich Suffolk  
Ipswich  
United Kingdom  
IP4 5PD

**Study participating centre**  
**Salford Royal Hospital**  
Salford Royal NHS Foundation Trust  
Stott Lane  
Salford Greater Manchester  
Salford  
United Kingdom  
M6 8HD

**Study participating centre**  
**Freeman Hospital**  
The Newcastle-Upon-Tyne Hospitals NHS Foundation Trust  
Freeman Road  
High Heaton  
Newcastle-Upon-Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**  
**Edinburgh Royal Infirmary Renal Department**  
51 Little France Drive  
Edinburgh  
United Kingdom  
EH16 4SA

**Study participating centre**  
**Bradford Royal Infirmary**  
Bradford Teaching Hospitals NHS Foundation Trust  
Duckworth Lane  
Bradford  
United Kingdom  
BD9 6RJ

**Study participating centre**

**University Hospitals Of North Midlands NHS Trust**  
Newcastle Road  
Staffordshire  
Stoke-On-Trent  
United Kingdom  
ST4 6QG

**Study participating centre**  
**Aberdeen Royal Infirmary Renal Unit**  
Foresterhill  
Aberdeen  
United Kingdom  
AB25 2ZN

**Study participating centre**  
**Queen Elizabeth University Hospital Renal Unit**  
1345 Govan Road  
Glasgow  
United Kingdom  
G51 4TF

**Study participating centre**  
**The Royal London Hospital**  
London  
United Kingdom  
E1 1BB

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

**Study participating centre**  
**Nottingham University Hospitals NHS Trust - City Campus**  
Nottingham  
United Kingdom  
NG5 1PB

**Study participating centre**  
**University Hospital Coventry**  
Coventry  
United Kingdom  
CV2 2DX

**Study participating centre**  
**Lister Hospital**  
Stevenage  
United Kingdom  
SG1 4AB

**Study participating centre**  
**St Luke's Hospital**  
Bradford  
United Kingdom  
BD5 0NA

**Study participating centre**  
**Royal Cornwall Hospital (Treliske)**  
Truro  
United Kingdom  
TR1 3LQ

**Study participating centre**  
**Manchester Royal Infirmary**  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre**  
**Kent & Canterbury Hospital**  
Canterbury  
United Kingdom  
CT1 3NG

**Study participating centre**  
**Guy's and St Thomas' NHS Foundation Trust**  
London

United Kingdom  
SE1 9RT

**Study participating centre**  
**Leicester General Hospital**  
Leicester  
United Kingdom  
LE5 4PW

**Study participating centre**  
**Derriford Hospital**  
Plymouth  
United Kingdom  
PL6 8DH

**Study participating centre**  
**City Hospitals Sunderland**  
Sunderland  
United Kingdom  
SR4 7TP

**Study participating centre**  
**Ninewells Hospital**  
Dundee  
United Kingdom  
DD1 9SY

**Study participating centre**  
**Victoria Hospital**  
Kirkcaldy  
United Kingdom  
KY2 5AH

**Study participating centre**  
**The James Cook University Hospital**  
Middlesbrough  
United Kingdom  
TS4 3BW

**Study participating centre**  
**Sheffield Teaching Hospitals**  
Sheffield  
United Kingdom  
S5 7AU

**Study participating centre**  
**Queen Alexandra Hospital**  
Portsmouth  
United Kingdom  
PO6 3LY

**Study participating centre**  
**Royal Liverpool and Broadgreen University Hospital**  
Liverpool  
United Kingdom  
L7 8XP

**Study participating centre**  
**Colchester General Hospital**  
Colchester  
United Kingdom  
CO4 5JL

**Study participating centre**  
**Oxford University Hospital**  
Headley Way  
Headington  
Oxford  
United Kingdom  
OX3 9DU

**Study participating centre**  
**Epsom and St Helier University Hospital**  
Dorking Road  
Epsom  
United Kingdom  
KT18 7EG

**Study participating centre**  
**St George's University Hospital**  
Blackshaw Road  
London  
United Kingdom  
SW17 0QT

**Study participating centre**  
**Worthing Hospital**  
University Hospitals Sussex NHS Foundation  
Lyndhurst Road  
Worthing  
United Kingdom  
BN11 2DH

## **Sponsor information**

**Organisation**  
North Bristol NHS Trust

**Sponsor details**  
Southmead Hospital  
Southmead Road  
Westbury-On-Trym  
Bristol  
England  
United Kingdom  
BS10 5NB

**Sponsor type**  
Hospital/treatment centre

**ROR**  
<https://ror.org/036x6gt55>

## **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**

Current publication and dissemination plan as of 16/12/2024:

Academic publications will be targeted at high impact general medical journals with presentations at leading nephrology conferences. Findings will also be used to inform future iterations of the NICE-approved UK Renal Association clinical guidelines and the European Renal Best Practice clinical guidelines.

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Previous publication and dissemination plan:

Academic publications will be targeted at high impact general medical journals such as the BMJ, the New England Journal of Medicine and the Journal of the American Medical Association. Findings will be presented at leading nephrology conferences in Europe (the ERA-EDTA Annual Congress) and North America (The American Society of Nephrology Kidney Week) as well as at the UK Kidney Week, co-hosted by the Renal Association and the multi-disciplinary British Renal Society. Findings will also be used to inform future iterations of the NICE-approved UK Renal Association clinical guidelines and the European Renal Best Practice clinical guidelines.

The H4RT protocol is available at reference URL: <https://www.journalslibrary.nihr.ac.uk/programmes/hta/158052/#/>

A statistical analysis plan approved by the trial steering committee will be made publicly available in due course.

**Intention to publish date**

28/02/2026

**Individual participant data (IPD) sharing plan**

The data sharing plans for the current study are unknown and will be made available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		27/06/2022	28/06/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No