

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)

Submission date 02/10/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/10/2017	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/09/2025	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

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 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 2026

Who is funding the study?

National Institute for Health and Care Research (UK)

Who is the main contact?

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Contact information

Type(s)

Public

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Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

227067

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 34704, IRAS 226067

Study information

Scientific Title

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

Acronym

H4RT

Study objectives

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)

South Central – Berkshire Research Ethics Committee, 07/09/2017, ref: 17/SC/0391

Study design

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

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

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(s)

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)

Key secondary outcome(s))

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)

Completion date

30/09/2026

Eligibility

Key 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

1553

Key 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

Date of first enrolment

01/11/2017

Date of final enrolment

08/09/2022

Locations

Countries of recruitment

United Kingdom

England

Scotland

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

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

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?
Protocol article		27/06/2022	28/06/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes