ISRCTN10997319 https://doi.org/10.1186/ISRCTN10997319

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

Registration date
10/10/2017

Overall study status
Ongoing

Last Edited
02/11/2023

Condition category
Urological and Genital Diseases

✓ Prospectively registered
✓ Protocol added
? SAP not yet added
– Results not yet expected
– Raw data not yet expected
✓ 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
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2. Prof Fergus Caskey
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Study website
http://www.bristol.ac.uk/population-health-sciences/projects/h4rt-trial/

Contact information

Type(s)
Public

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Type(s)

Scientific

Contact name
Prof Fergus Caskey

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
227067

ClinicalTrials.gov number
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 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)

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

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
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
30/09/2025

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