

Randomised evaluation of sodium dialysate levels on vascular events

Submission date 10/01/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/03/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/08/2025	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

In the UK 8000 people a year suffer permanent kidney failure and start dialysis. Dialysis sustains life, but at enormous cost, both in terms of healthcare spending and more importantly in terms of poor quality of life and drastically shortened life expectancy. The most common form of dialysis, haemodialysis, cleans the blood and removes excess water, but must be performed three times a week. It is a difficult and unpleasant treatment, with many patients continuing to suffer from excess fluid build-up, swelling, shortness of breath and fatigue. In addition, the build-up of salt (sodium) contributes to the high rates of heart attacks, strokes, and heart failure that affect people receiving long-term dialysis.

Currently, most dialysis centres set the dialysate sodium (the amount of salt in the fluid that washes the blood) between 135 mmol/l and 140 mmol/l and all patients in a given centre will have the same (default) dialysis sodium set on their machines for each session. Small studies suggest that sodium levels closer to the lower end of this range may increase the removal of excess salt from the body and reduce fluid build-up, which in turn may reduce the risks of heart disease and strokes. However, these same studies also suggest that levels closer to the upper end of the range may make the dialysis procedure more stable and lower the chance of blood pressure dropping during the dialysis session. This study will determine if a lower or higher dialysate sodium setting is preferable in terms of improving heart health and life expectancy.

Who can participate?

Dialysis units that mostly dialyse adults (aged 18 years old and over) receiving maintenance haemodialysis

What does the study involve?

Dialysis units are randomly allocated to use either a dialysate sodium of 137mmol/l or a dialysate sodium of 140mmol/l for about 3 years. Using information collected by the NHS and the UK Renal Registry, the number of people at each centre suffering a heart attack, stroke, heart failure, hospitalisation and death will be tracked to determine what is the best sodium setting to use to benefit the greatest number of patients.

What are the possible benefits and risks of participating?

This is a pragmatic study so there are no additional risks to the participants. The benefits are for

forthcoming participants who undergo dialysis as this may provide an accurate national default sodium level.

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

When is the study starting and how long is it expected to run for?
June 2022 to May 2026

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

Who is the main contact?
Dr Rumana Jalil-Rahman, cctu.resolve@ucl.ac.uk

Study website
<https://www.resolve-trial.co.uk>

Contact information

Type(s)
Scientific

Contact name
Dr Hannah Sims

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
317616

ClinicalTrials.gov number
NCT02823821

Secondary identifying numbers
CPMS 53987, IRAS 317616

Study information

Scientific Title

Randomised Evaluation of SODium dialysate Levels on Vascular Events

Acronym

RESOLVE

Study objectives

This global study will establish whether treatment with a default dialysate sodium concentration of 137 mmol/l compared with 140 mmol/l reduces major cardiovascular events and death in adult patients receiving haemodialysis in centres employing a default dialysate sodium.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 01/11/2022, South Central - Berkshire Research Ethics Committee (Bristol REC Centre, Temple Quay House, 2 The Square, Temple Quay, Bristol, BS1 6PN, UK; +44 (0)207 104 8178, +44 (0)207 104 8182; berkshire.rec@hra.nhs.uk), ref: 22/SC/0280

Study design

Randomized; Interventional; Design type: Treatment, Other

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Renal disorders

Interventions

The RESOLVE study will randomly allocate 100 dialysis units across the UK to use either a dialysate sodium of 137mmol/l or a dialysate sodium of 140mmol/l for approximately 3 years. Using information collected by the NHS and the UK Renal Registry, the number of people at each centre suffering a heart attack, stroke, heart failure, hospitalisation and death will be tracked to determine what is the best sodium setting to use to benefit the greatest number of patients.

1. Study posters and patient leaflets will be available in the participating dialysis units. Additional information can be requested from unit staff and a 'Study Information Sheet' will be available. In addition, the study posters and patient leaflets will have a QR code with a link to the RESOLVE UK website where further information will be available about the study.
2. At this point patients can decide to opt out of data collection.
3. If the patient decides to allow data collection, then this visit and future visits to the unit will remain as normal. The duration and timing of dialysis will be unchanged.
4. Baseline data will be collected on patients, who don't opt-out, from existing unit records. This does not require any input from the patients.
5. Site will be randomised.
6. Site will change its machines to use the allocated dialysate sodium as a default.
7. As all study data will be extracted from routine clinical data collection systems or registries (namely the UK Renal Registry and NHS Digital), participants will not be subjected to any additional questionnaires, medical tests, physical examinations or doctor's visits.
8. All patients at the site (regardless of whether they opt out or not) will receive the allocated dialysate sodium per usual unit practice unless their doctor directs that a different sodium dialysate be prescribed. Patients who do not opt out, and who have their dialysate sodium individualised will remain in the study to maximise study generalisability and ensure a valid answer to the primary research question that concerns whether patient outcomes differ between units employing a higher or lower dialysate sodium.

Intervention Type

Other

Phase

Phase IV

Primary outcome measure

The composite of hospitalised myocardial infarction, hospitalised stroke, and all-cause death, all measured using NHS Digital data at annual timepoints

Secondary outcome measures

1. Hospitalised heart failure measured using NHS Digital data at annual timepoints
2. The time between these events (hospitalised acute myocardial infarction, hospitalised stroke, hospitalised heart failure and death) measured using NHS Digital data at annual timepoints
3. Health economics will be performed to calculate potential costs and health-related outcomes in patients undergoing dialysis with a sodium concentration of 137 mmol/l vs sodium concentration of 140 mmol/l over the duration of the study

Overall study start date

01/06/2022

Completion date

01/05/2026

Eligibility

Key inclusion criteria

The principal SITE inclusion criteria are dialysis units that:

1. Predominantly dialyse adults (≥ 18 years old) receiving maintenance haemodialysis
2. Rates of withdrawal within the first two years of commencing dialysis for social reasons have

been less than 15% for the 2 years prior to recruitment and are not expected to increase above 15%

3. Has a minimum of 10 dialysis recipients at the time of randomisation

4. Utilises a default dialysate sodium concentration at the time of recruitment (i.e. a substantial majority of dialysis sessions are conducted with the default dialysate sodium concentration)

5. Is a self-contained unit (i.e. unit patients do not regularly rotate through another unit. Brief trips by patients to a parent or other unit do not exclude a site). Note: If two or more sites have regularly rotating patients, these sites may be randomised together as a cluster.

6. Willing to accept randomisation to either intervention (as determined by the nominated Director of Unit)

7. Is not a home dialysis training or support unit (sites that include both in-centre or satellite dialysis patients and home patients may participate but the study procedures and assessments will only be conducted in the in-centre/satellite component of the site)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 100; UK Sample Size: 100

Key exclusion criteria

The principal SITE exclusion criteria are dialysis units that are:

1. Not able to comply with data collection methods

Date of first enrolment

27/03/2023

Date of final enrolment

31/07/2024

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Royal Free London NHS Foundation Trust

Royal Free Hospital

Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
Royal Devon University NHS Ft
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
East Kent Hospitals University NHS Foundation Trust
Kent & Canterbury Hospital

Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Study participating centre

St George's University Hospitals NHS Foundation Trust

St George's Hospital
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre

Sheffield Teaching Hospitals NHS Foundation Trust

Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre

East and North Hertfordshire NHS Trust

Lister Hospital
Coreys Mill Lane
Stevenage
United Kingdom
SG1 4AB

Study participating centre

Northern Care Alliance NHS Foundation Trust

Salford Royal
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre

Imperial College Healthcare NHS Trust

The Bays
St Marys Hospital

South Wharf Road
London
United Kingdom
W2 1BL

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
The Shrewsbury and Telford Hospital NHS Trust
Mytton Oak Road
Shrewsbury
United Kingdom
SY3 8XQ

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Walsgrave General Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Kings College Hospital NHS Foundation Trust
Kings College Hospital
Denmark Hill

London
United Kingdom
SE5 9RS

Study participating centre

Epsom and St Helier University Hospitals NHS Trust

St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre

East Suffolk and North Essex NHS Foundation Trust

Colchester Dist General Hospital
Turner Road
Colchester
United Kingdom
CO4 5JL

Study participating centre

The Royal Wolverhampton NHS Trust

New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre

University Hospitals Birmingham NHS Foundation Trust

Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre

University Hospitals Sussex NHS Foundation Trust

Worthing Hospital

Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

Study participating centre

Mid and South Essex NHS Foundation Trust

Prittlewell Chase
Westcliff-on-sea
United Kingdom
SS0 0RY

Study participating centre

York and Scarborough Teaching Hospitals NHS Foundation Trust

York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre

Hull University Teaching Hospitals NHS Trust

Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre

Gloucestershire Hospitals NHS Foundation Trust

Cheltenham General Hospital
Sandford Road
Cheltenham
United Kingdom
GL53 7AN

Study participating centre

James Paget University Hospitals NHS Foundation Trust

Lowestoft Road
Gorleston
Great Yarmouth

United Kingdom
NR31 6LA

Study participating centre

Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre

Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Sponsor information

Organisation

University College London

Sponsor details

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Comprehensive Clinical Trials Unit
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United Kingdom
WC1V 6LJ
+44 (0)2035495499
l.c.webber@ucl.ac.uk

Sponsor type

University/education

Website

<http://www.ucl.ac.uk/>

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Government

Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR134660

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/05/2027

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?
HRA research summary			28/06/2023	No	No