ISRCTN11342007 https://doi.org/10.1186/ISRCTN11342007

Bio-impedance spectroscopy to maintain renal output

Submission date	Recruitment status	[X] Prospectively registered
25/04/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
26/04/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/08/2025	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Most patients who develop kidney failure choose unit-based haemodialysis treatment. One of the main functions of dialysis is to control the amount of fluid in the body. Too much fluid can lead to persistently raised blood pressure that damages he heart and increases the risk of stroke, and may cause fluid to collect in the lungs leading to breathing difficulties which if allowed to get out of control could result in death. Too little fluid causes dehydration, cramps and low blood pressure on dialysis and more rapid or complete loss of any remaining kidney function along with its associated benefits. Bioimpedance is a simple, bedside measurement giving information about body composition, in particular how much excess fluid is present. Clinicians can use this to guide how much fluid should be removed from the body in conjunction with the normal clinical assessment of the amount of fluid in the body, but it is not known if this results in better decisions and outcomes for patients. The bioimpedance information can be shared with patients to help them understand the objectives of their treatment, potentially improving confidence in how their dialysis care is managed. The research is to test whether taking regular measurements with a bioimpedance device improves outcomes for people who have recently started haemodialysis treatment for kidney failure. In particular, the study aims to see if this helps patients maintain their remaining kidney function, as this is associated with improved survival, fewer symptoms of kidney failure, fewer side effects of dialysis treatment and a better quality of life including confidence in managing their health, and cost benefit analysis.

Who can participate?
Adults (aged at least 18) starting kidney dialysis due to advanced kidney disease.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are regularly assessed with a bioimpedance device as well as receiving standard treatment. Those in group 2 receive standard treatment only. All participants are assessed at the start of the study, then once a month for three months. Assessments then continue every other month for up to the next 20 months. These assessments compare between the two treatments how quickly kidney

function is declining, the side effects of treatment, symptoms of kidney failure, blood pressure and heart function, how confident the patient feels regarding managing their own health and the costs involved.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Keele University Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
June 2016 to July 2023

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

Who is the main contact?
Prof. Simon Davies
NSTCCG.BISTRO@nhs.net

Contact information

Type(s)
Scientific

Contact name
Prof Simon Davies

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Additional identifiers

Study information

Scientific Title
Bio-Impedance Spectroscopy To maintain Renal Output: a randomised controlled trial

Acronym
BISTRO

Study objectives

The aim of the research is to determine if incorporation of bioimpedance into the setting of the post dialytic weight reduces loss of residual kidney function in incident centre-based HD patients, with the potential to improve clinical outcomes, in particular dialysis related symptoms, hospitalisation and survival.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland REC 2, 12/09/2016, ref: 16/NS/0094

Primary study design
Interventional

Study design
Pragmatic multi-centre open-label prospective randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Urological and Genital Diseases

Interventions
Patients starting haemodialysis as an outpatient who still have some remaining kidney function will be invited to participate in a clinical trial that compares current best practice with the same but additionally guided by regular bioimpedance measurements. The trial will randomly assign, 516 patients from 30 dialysis units across the UK. The random allocation will be 1:1 to the Bioimpedance intervention and control groups, stratified by centre (main or satellite centre, where dialysis will commence) and planned versus unplanned start.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
Time to anuria (loss of urine output), <100ml/day or 200ml in the short inter-dialytic period confirmed by a further collection after 2 weeks to exclude temporary illness.

To measure the primary outcome urine volume and residual renal clearances to be measured at baseline, monthly for 3 months and alternate months (for up to a further 20 months) until trial completion, or the primary endpoint is reached.

Key secondary outcome(s)

Determining the effect of the use of bioimpedance in assessing the amount of fluid in the body to guide the setting of the post-dialytic target weight on:
1. The rate that kidney function reduces (baseline, monthly for 3 months, then alternate months for up to 20 months)
2. Vascular access failure, cardiovascular events, hospital admissions, death and including the use of routinely collected data from the UK Renal Registry, Hospital episode Statistics and the Office for National Statistics (and equivalent bodies in Wales, Scotland and Northern Ireland) via the UK Renal Registry. These are measured at baseline, and at the end of the study, routine clinical data collected by dialysis units for the UK Renal Registry returns will be made available for this study. Death will be recorded in real time during the study
3. Measures of dialysis efficacy and safety (body fluid assessment, blood pressure). These are measured at baseline, monthly for 3 months, then every 3 months for up to a further 20 months
4. Patient reported outcomes including quality of life, dialysis symptoms, functional status. These are measured at baseline, then 3 monthly for up to 24 months

Completion date
31/07/2023

Eligibility

Key inclusion criteria
1. Adults aged >18 years commencing centre-based maintenance haemodialysis due to advanced kidney disease CKD stage 5, planned or unplanned, via arterio-venous fistula, graft or central venous catheter (i.e. with or without permanent vascular access)
2. Commencing dialysis on any regimen, including having incremental dialysis initiation
3. Residual kidney function: For patients who have not yet started dialysis treatment they should have a daily urine volume > 500ml/day and/or a or a measured mean urea and creatinine clearance >3ml/min/1.72m2 determined from a 24 hour collection; for patients already on dialysis they should have a urine volume >500ml during the short inter-dialytic period and/or a measured mean urea and creatinine clearance >3ml/min/1.72m2, determined from the same timed inter-dialytic urine collections and an average of the post- and pre-dialysis plasma urea and creatinine concentrations.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment

438

Key exclusion criteria
1. Unable or unwilling to give informed consent
2. Unable to comply with trial procedures, e.g. collection of urine output
3. Likely survival prognosis or planned modality transfer < 6 months
4. Subjects with limb amputations when the foot is not accessible AND it is not possible to take hand to hand measurements

Date of first enrolment
17/04/2017

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Keele University
Keele University Clinical Trials Unit
Arthritis Research UK Primary Care Centre
Research Institute for Primary Care Sciences
Staffordshire
United Kingdom
ST5 5BG

Sponsor information

Organisation
Keele University

ROR
https://ror.org/00340yn33

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 datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Simon Davies (use both email addresses: medicine.datasharing@keele.ac.uk and s.j.davies@keele.ac.uk).
Type of data: electronic deidentified trial data are available for request in aggregated format or at the level of the individual participant.
Data availability: data will become available from Summer 2024 until 2031.
Access criteria data: a data request form is required to be completed and must outline the type of data to be obtained, the reason for obtaining this data (research question/objective), the timing for when the data is required to be available (start date/end date). Checks will be performed by a Data Custodian and Academic Proposals (DCAP) committee at Keele to ensure that the data set requested is appropriately suited to answer the research question/objective and that the request fits with the original ethical approval and participant consent and adheres to funder and legal restrictions.
Additional information: following an application by researchers who can demonstrate the capacity to undertake their pre-specified data analysis for what types of analyses; inclusion of data in participant level of summary-level meta-analyses; analyses of secondary outcomes not already undertaken by the research team and by what mechanism; formal application whether consent from participants was obtained; this was obtained, comments on data anonymisation; data will be in a fully anonymised format.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/05/2023	24/07/2024	Yes	No
Results article		01/07/2025	05/08/2025	Yes	No
Protocol article	protocol	26/04/2017		Yes	No

HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results		01/07/2025	05/08/2025	No	Yes
Statistical Analysis Plan	version 3	06/07/2021	24/07/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes