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A pilot study investigating the benefits of a new form of nutritional supplement called “immuno-nutrition” on muscle mass and strength in people on haemodialysis

Submission date
18/06/2026

Recruitment status
Recruiting

Registration date
02/07/2026

Overall study status
Ongoing

Last Edited
01/10/2026

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Low muscle mass and strength (sarcopenia) are common problems in people receiving haemodialysis which lead to poor quality of life and a higher risk of death.
Inflammation, caused by the body’s defence (immune) system being activated in response to infection or injury, is another common factor that causes loss of muscle mass and strength in people on haemodialysis.
Standard food supplements are not effective at increasing muscle mass and strength in people on haemodialysis. This is because inflammation limits protein from food being converted into muscle.
“Immuno-nutrition” is a new form of food supplement that provides calories and protein like other standard food supplements but also contains extra nutrients that reduce inflammation. In previous studies, immuno-nutrition has been shown to benefit people with cancer, another patient group with high inflammation.
Recently, we showed that immuno-nutrition improved muscle strength and decreased inflammation in a small study of 14 people on haemodialysis.
Therefore, the aim of this research is to test the study methods and procedures and to collect information that will help us design a larger, more detailed study in the future.

Who can participate?
Patients aged 18 years and over who are receiving three haemodialysis sessions per week for at least 3 hours, whose blood tests show that their potassium levels are normal, and who are not taking any medication that inhibits their immune system.

What does the study involve?
Participants will be randomly assigned (similar to picking names from a hat) to the intervention group (“immuno-nutrition”) or the usual care group (standard food supplement). Both groups will take one supplement daily for 24 weeks.
The following assessments will be made at the start of the study and after 12, 18 and 24 weeks

of taking the supplements:
1. Handgrip strength, a measure of muscle strength.
2. Body levels of fat and muscle using a specialist scale.
3. Physical function (walking speed, ability to stand from a chair, balance)
4. Food intake (3-day food diaries)
5. Quality of life (questionnaire)
6. Blood tests to monitor blood chemistry and inflammation

What are the possible benefits and risks of participating?
The study will involve taking an immuno-nutrition supplement or a standard nutritional supplement (usual care), as well as following usual dietetic advice provided by NHS renal dietitians, all of which are not expected to be associated with any risks. However, if participants experience anything untoward, the research team will record this, and they will be closely monitored until it has resolved. Participants will also be monitored regularly to ensure that they are taking the nutritional supplements.
We do not foresee any disadvantages arising from taking part in this study, other than the time the participants give for the study assessments, which will be arranged to take place when participants attend for their routine haemodialysis treatment.
The information we get from this study will help us design and conduct a larger, more detailed study to test the effect of immuno-nutrition on muscle mass and strength, inflammation, and associated beneficial outcomes. We cannot promise any immediate direct benefit to research participants; however, by taking part in the study assessments, participants will be able to monitor how their bodies respond to the supplements.

Where is the study run from?
This study is being conducted at the Royal Derby Hospital renal dialysis unit and Lichfield dialysis centre, which are part of University Hospitals of Derby and Burton NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2026 to July 2027

Who is funding the study?
The National Institute for Health and Care Research (NIHR) as part of the Research for Patient Benefit Programme (UK)

Who is the main contact?
Dr Daniela Viramontes Hörner, mszdv@nottingham.ac.uk

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Integrated Research Application System (IRAS)
350071

Central Portfolio Management System (CPMS)
65366

National Institute for Health and Care Research (NIHR)
209189

Study information

Scientific Title
Effect of immuno-nutrition on markers of sarcopenia and systemic inflammation in a haemodialysis population: a feasibility randomised controlled trial

Acronym
IMMUNOSH

Study objectives
Primary objectives:
1. To assess the feasibility of recruitment and randomisation to the trial
2. To assess adherence, safety and acceptability of the intervention
3. To evaluate the feasibility of conducting the trial at the participating location
4. To assess the effect of different durations of intervention to identify the optimum period for a future trial
5. To determine the optimal primary endpoint for a future trial

Secondary objectives:
To investigate the effect of immuno-nutrition on muscle strength, body composition, physical performance, prevalence of sarcopenia, dietary intake, biochemical blood variables, inflammatory markers and health-related quality of life.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/07/2026, East Midlands – Nottingham 2 Research Ethics Committee (Health Research Authority (HRA), 2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0) 207 104 8065; nottingham2.rec@hra.nhs.uk), ref: 26/EM/0133

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Renal failure

Interventions
This is a feasibility study that will be conducted in the Royal Derby Hospital renal dialysis unit and Lichfield dialysis centre.

Participants will be randomly assigned (similar to picking names from a hat) to the intervention group ("immuno-nutrition") or the usual care group (standard food supplement). Both groups will take one supplement daily for 24 weeks.

Potential participants will be identified by members of the usual healthcare team (which may include members of the research team). Then, a member of the research team will meet with potential participants in person (during their haemodialysis session) to provide the initial details of the study and participant information sheet (PIS).

Participants will then be given at least 48 hours to consider whether they wish to participate before being re-contacted by a member of the research team (i.e., during the participant's next haemodialysis session). If participants wish to take part in the study, a member of the research team will discuss the PIS further if needed and give participants the opportunity to ask questions.

Once participants have agreed to take part in the study, the usual care group will take daily one bottle (125 ml) of Fortisip Compact Protein® (standard food supplement) for 24 weeks, and the intervention group will take daily one sachet (74 g) dissolved in 125 ml of water of an immuno-nutrition supplement (Oral Impact®, Nestle) for 24 weeks.

Participants in both groups will continue to receive individualised dietetic advice delivered by the NHS renal dietitians who are members of the participants' usual clinical care team.

Consumption of both food supplements will be supervised during haemodialysis sessions (thrice weekly) and self-reported (written and counting returned sachets/bottles) on non-dialysis days to assess adherence. Participants will receive precise instructions on how and when to take the supplements with close monitoring by the research team to encourage adherence.

Before participants start taking both supplements, the research team will collect information from participants' medical records about their age, ethnicity, civil status, religion or belief, socioeconomic status, medical conditions/history and current medication and will also conduct an assessment of frailty.

The following assessments will be made at the start of the study and after 12, 18 and 24 weeks of taking the supplements:
1. Muscle strength (handgrip strength)
2. Levels of fat and muscle within the body using a specialist scale.
3. Physical function (walking speed, ability to stand from a chair, balance)
4. Food intake via food diaries (one dialysis day, one non-dialysis day and one weekend day)
5. Quality of life (via a questionnaire)
6. Blood tests to monitor blood chemistry and inflammation. The research team will collect the

results of the blood tests that participants usually have done every month as part of their haemodialysis treatment and will also collect and store approximately two teaspoons of blood to measure some molecules that indicate inflammation. The research team will take the blood before a usual haemodialysis session so no extra needle puncture will be required. These blood samples will be stored in a freezer until they are analysed in a laboratory.

The research team will also collect information regarding whether potential participants met eligibility criteria or not; the reasons for not being eligible for study participation; or if they were eligible but declined participation (with reasons if provided), as well as the number of participants who completed the study and assessments and reasons for non-completion.

Acceptability of both the immuno-nutrition and standard food supplements will be assessed through participant interviews after the end of the study at week 24.

Safety of both supplements will be assessed by reporting of adverse events during the study, participant-reported tolerability (presence/absence of gastrointestinal symptoms, e.g vomiting, diarrhoea) and monitoring of blood potassium levels (a blood sample will be taken fortnightly for the first month after commencing treatment in both groups and then once a month until the end of the study at week 24).

Intervention Type
Supplement

Primary outcome(s)
The feasibility of conducting a randomised controlled trial of immuno-nutrition vs standard nutritional supplementation. Feasibility outcomes will include the following:
1. Screening: the number of patients who are screened will be provided as a total, measured during recruitment before baseline assessment
2. Eligibility rate: defined as the proportion of eligible patients out of the total number of patients screened, measured during recruitment before baseline assessment
3. Approach rate: defined as the proportion of patients approached out of the total number of eligible patients, measured during recruitment before baseline assessment
4. Consent rate: defined as the proportion of patients who provide informed consent out of the total number of patients approached, measured during recruitment before baseline assessment
5. Refusal rate: defined as the proportion of patients who refuse to take part in the study out of the total number of patients approached, measured during recruitment before baseline assessment
6. Randomisation rate: defined as the proportion of patients who get randomised to take part in the study out of the total number of patients approached, measured during recruitment before baseline assessment
7. Completion rates: completion of each outcome assessment will be calculated at each appropriate study visit. This is defined as the number of participants completing the assessment out of the participants who are still expected to complete the assessment at that visit (i.e., those who remain in the trial and have not withdrawn consent for follow-up assessments). Measured at baseline, 12, 18 and 24 weeks.
8. Adherence rate: calculated for each participant as the proportion of daily doses taken out each month throughout 24 weeks and overall. Adherence rate will be reported as the proportion of participants who meet the pre-specified adherence threshold of 75%. Measured at 4, 8, 12, 16, 20 and 24 weeks
9. Acceptability of both nutritional supplements will be assessed using a semi-structured written questionnaire on completion of the treatment period at week 24, including questions about

perceptions of taste, smell and consistency of both nutritional supplements, as well as questions to assess participants' opinions on long-term intake of the supplements.
10. Safety outcomes:
10.1. Reporting of adverse events during the trial and participant-reported tolerability of both nutritional supplements will be monitored daily throughout the intervention period (i.e., after baseline assessment to 24 weeks). Tolerability will be assessed by the presence/absence of gastrointestinal symptoms (e.g., nausea, vomiting, diarrhoea, and bloating).
10.2. Serum potassium levels will be measured using a pre-dialysis blood sample taken at screening, baseline, 15 days, and 4, 8, 12, 16, 20 and 24 weeks

Key secondary outcome(s)
1. Muscle strength will be assessed with handgrip strength at baseline, 12, 18 and 24 weeks
2. Body composition will be assessed with bioelectrical impedance analysis at baseline, 12, 18 and 24 weeks
3. Physical performance will be assessed with the Short Physical Performance Battery at baseline, 12, 18 and 24 weeks
4. Prevalence of sarcopenia and severe sarcopenia will be reported according to the definition from the European Working Group on Sarcopenia in Older People at baseline, 12, 18 and 24 weeks
5. Dietary intake will be assessed with 3-day food diaries at baseline, 12, 18 and 24 weeks
6. Routine blood samples will be taken at baseline, 12, 18 and 24 weeks and be transferred to the local NHS laboratory for routine biochemistry and haematology testing, including haemoglobin, urea, creatinine, potassium, phosphate, calcium, albumin, total protein and parathyroid hormone
7. Systemic inflammation will be assessed with plasma levels of pro-inflammatory cytokines (interleukin [IL]-6 and IL-8) analysed via enzyme-linked immunosorbent assays at baseline, 12, 18 and 24 weeks
8. Health-related quality of life will be assessed using the Kidney Disease Quality of Life 36-item short-form survey at baseline, 12, 18 and 24 weeks

Completion date
31/07/2027

Eligibility

Key inclusion criteria
1. Aged >=18 years (no upper age limit)
2. Dialysis regime of >=3 haemodialysis sessions/week for >=3 hours using biocompatible dialysers
3. Able to give informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit

100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Treatment with immunosuppressant drugs
2. Body mass index (BMI) >35 kg/m²
3. Pregnancy, breastfeeding or intending pregnancy
4. Expected survival <6 months (prognosis assessed and determined by an experienced consultant nephrologist)
5. Hospitalisation at time of screening
6. Known intolerance/allergy to either supplement (or isolated ingredients)
7. Pre-dialysis serum potassium >5.3 mmol/l

Date of first enrolment
28/09/2026

Date of final enrolment
31/01/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Derby and Burton NHS Foundation Trust
Royal Derby Hospital
Uttoxeter Road
Derby
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DE22 3NE

Sponsor information

Organisation
University Hospitals of Derby and Burton NHS Foundation Trust

ROR

https://ror.org/04w8sxm43

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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 and/or analysed during the current study will be stored in a non-publicly available repository and will be available from the sponsor upon reasonable request.

Contact for access:
Requests should be directed to the study Sponsor, University Hospitals of Derby and Burton (UHDB) NHS Foundation Trust, via email to uhdb.sponsor@nhs.net.

Repository/storage location:
The dataset will be securely held in a validated electronic data capture system managed by the Derby Clinical Trials Support Unit (DCTSU).

Type of data available:
Anonymised Individual Participant Data (IPD) will be shared. This includes the full quantitative dataset (muscle strength, body composition, physical performance, prevalence of sarcopenia, dietary intake, blood biochemistry and haematology [including haemoglobin, urea, creatinine, potassium, phosphate, calcium, total protein, parathyroid hormone], inflammation [cytokine analysis], and health-related quality of life).

Availability timeline:
Data will be available for request 12 months after the publication of the study's main findings and will remain available for a period of 5 years.

Access criteria:
Data will be shared with bona fide researchers at academic or non-commercial institutions for the purpose of ethically approved, non-commercial secondary research. A legally binding data sharing agreement must be executed before any data is transferred.

Access mechanism:
Researchers must submit a formal written proposal outlining their research plan and ethical approval. Requests will be reviewed by a Data Access Committee, with final approval from UHDB.

Consent and anonymisation:
Consent for sharing anonymised data for future research was obtained from all participants. The dataset will be fully anonymised by removing all direct identifiers (e.g., names, NHS numbers, and contact details) and key indirect identifiers to minimise the risk of re-identification.

Ethical or legal restrictions:
The use of the data is strictly governed by the terms of the Data Sharing Agreement, which prohibits any attempt to re-identify participants. All data sharing will comply with UK GDPR and the Data Protection Act 2018.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	30/06/2026	09/09/2026	No	Yes
Protocol file	version 2.0	30/06/2026	09/09/2026	No	No