ISRCTN89178223 https://doi.org/10.1186/ISRCTN89178223

Pre-emptive rehabilitation to prevent dialysis-associated morbidity

Submission date
19/03/2018

Recruitment status
No longer recruiting

Registration date
20/03/2018

Overall study status
Completed

Last Edited
27/03/2019

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Chronic kidney disease is a long-term condition where the kidneys don't work as well as they should. Dialysis treatment to replicate some of the kidney's functions may be necessary in advanced cases. Chronic kidney disease and dialysis often lead to frequent hospital admissions, and are associated with increased lethargy (tiredness), muscle wasting, reduced independence and poorer quality of life. Increased exercise, improved nutrition, and education before patients start dialysis can help maintain independence and improve health on starting dialysis. This study aims to investigate whether regular exercise, good nutrition and education, commencing before dialysis starts and continuing for the first 6 months of dialysis, leads to greater improvements in exercise ability, independence, and quality of life, than usual care.

Who can participate?
Patients aged 18 and over who are expected to start dialysis within the next 12 months

What does the study involve?
All participants attend an appointment for exercise tests to measure muscle function and exercise ability, scans to measure muscle mass, and to complete questionnaires to assess appetite and quality of life. Participants are then randomly allocated to the treatment group or usual care group. The treatment group involves a 10-week exercise and education programme. Each session lasts for 2 hours, with an hour of exercise followed by an education session that aims to help participants to cope better with dialysis. Participants are given an individual exercise and care plan to follow. The exercise and education sessions continue once per month until starting dialysis, and for the first 6 months of dialysis. Participants in the usual care group continue with usual clinic appointments and dialysis. The assessments done at the start of the study are repeated at several timepoints throughout the study, before and after starting dialysis. Results from these assessments are compared between the groups to assess whether this treatment is better than usual care at maintaining independence and quality of life in patients starting dialysis.

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

Where is the study run from?
1. Royal Derby Hospital (UK)
2. Nottingham University Hospitals City Hospital Campus (UK)

When is the study starting and how long is it expected to run for?
March 2016 to June 2020

Who is funding the study?
Kidney Research UK

Who is the main contact?
Fiona Willingham

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
35594

Study information

Scientific Title
Pre-emptive rehabilitation to prevent dialysis associated morbidity (PREHAB-2): a study to assess the impact of exercise, nutritional intervention and multidisciplinary education upon outcomes in patients approaching and commencing dialysis

Acronym

PREHAB-2

Study objectives
Chronic kidney disease and dialysis often lead to frequent hospital admissions, and are associated with increased lethargy, muscle wasting, reduced independence and poorer quality of life. Previous work from our unit shows that increased exercise, improved nutrition, and education, before patients start dialysis, can help maintain independence, and improve health on starting dialysis.

This project aims to investigate whether regular exercise, good nutrition, and education, commencing before dialysis starts and continuing for the first 6 months of dialysis, leads to greater improvements in exercise ability, independence, and quality of life, than usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Derby Research Ethics Committee (REC), 04/10/2017, ref: 17/EM/0290

Study design
Randomised; Interventional; Design type: Prevention, Process of Care, Education or Self-Management, Dietary, Psychological & Behavioural, Complex Intervention, Physical

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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 failure

Interventions
Patients expected to start dialysis within the next 12 months will be invited to take part. Patients who agree to take part will be asked to sign a consent form. All participants attend an initial assessment appointment, for exercise tests to measure muscle function and exercise ability, scans to measure muscle mass, and to complete questionnaires to assess appetite and quality of life. Participants are then randomly allocated to the treatment group or usual care group.

The treatment group involves a 10-week exercise and education programme. Each session lasts for 2 hours, with an hour of exercise, followed by an education session, which aims to help participants to cope better with dialysis. Participants will be given an individual exercise and care plan to follow. The exercise and education sessions continue once per month until starting dialysis, and for the first 6 months of dialysis.

Participants in the usual care group continue with usual clinic appointments and dialysis.

The assessments done at the beginning of the study are repeated at several timepoints throughout the study, before and after starting dialysis. By comparing results from these assessments between the groups, we can assess if this treatment is superior to usual care in maintaining independence and quality of life in patients starting dialysis.

Intervention Type
Other

Primary outcome measure
Functional and exercise capacity, determined by the Incremental Shuttle Walk Test; Timepoint (s): End of the study

Secondary outcome measures
1. Objective changes in functional capacity, determined by increased muscle mass, strength and function, will be assessed using the short physical performance battery test, single repetition maximum for leg extension and bicep curl, and one minute sit to stand, will be measured at baseline, 3 months, upon starting dialysis, and at 3, 6 and 12 months after starting dialysis
2. Objective and subjective changes in nutritional status will be measured using a combination of validated methods, including weight, body mass index (BMI) and percentage weight change, mid upper arm circumference, handgrip strength, dietary intake and appetite assessment, and subjective global assessment of nutritional status will be assessed at baseline, 3 months, upon starting dialysis, and at 3, 6 and 12 months after starting dialysis
3. Subjective changes in functional and exercise capacity, determined by patient perception of functional capacity using the Duke Activity Status Index (DASI) questionnaire, and exercise self-efficacy score will be measured at baseline, 3 months, upon starting dialysis, and at 3, 6 and 12 months after starting dialysis
4. Subjective improvement in quality of life, determined by DASI questionnaire, Patient Activation Measure, Renal Distress Thermometer, FACIT-Fatigue Score, Hospital Anxiety and Depression Scale (HADS), and nested qualitative interview studies will be measured at baseline, 3 months, upon starting dialysis, and at 3, 6 and 12 months after starting dialysis
5. Changes in body composition will be measured using DEXA scans and muscle ultrasound scans at baseline, 3 months, upon starting dialysis, and at 3, 6 and 12 months after starting dialysis
6. The presence of oxidative stress and assessment of cardiovascular risk will be measured from levels of advanced glycation end products (AGEs) via skin autofluorescence at baseline, 3 months, upon starting dialysis, and at 3, 6 and 12 months after starting dialysis

Overall study start date
01/03/2016

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Male and female aged 18 years and above
2. eGFR less than 15mls/min
3. Rate of change in eGFR indicates that dialysis will be initiated within 12 months from commencing the study
4. Attending the low clearance clinic
5. Patient has opted for dialysis
6. Patient is able to exercise

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Patient is not predicted to require dialysis within 12 months of commencing the study
2. Patient has chosen conservative care rather than opting for dialysis
3. Severe physical impairment and/or significant comorbidity that makes exercise impossible or unsafe, defined by exercise-induced angina, inability to walk less than 50 metres, or dyspnoea with effort
4. Insufficient command of English to provide informed consent or comply with the testing protocol and exercise and education component (if results indicate the intervention to be beneficial, future studies will include provision for such patients)
5. Patient is pregnant (therefore is unable to undergo Dual X-Ray Absorption (DEXA) Scan)

Date of first enrolment
01/04/2018

Date of final enrolment
31/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Derby Hospital (lead centre)
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Nottingham University Hospitals City Hospital Campus
Hucknall Road
Nottingham
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NG5 1PB

Sponsor information

Organisation
Derby Teaching Hospitals NHS Foundation Trust

Sponsor details
Royal Derby Hospital
Uttoxeter Road
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Charity

Funder Name
Kidney Research UK (KRUK); Grant Codes: AHPF_004_20160729

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Study protocol currently being finalised for submission to a peer-reviewed journal. The study results will be published in an appropriate high impact peer-reviewed journal, around one year after the end of the trial. Results will also be presented at national and international conferences, and disseminated to the patients and public, via social media, newsletter articles, and presentation at patient conferences and forums, and also to the clinical teams in participating centres.

Intention to publish date
30/06/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No