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Clinical value and cost-effectiveness of intra-dialytic exercise for the improvement of health-related quality of life in people with stage 5 chronic kidney disease undergoing maintenance haemodialysis

Submission date
11/12/2014

Recruitment status
No longer recruiting

Registration date
17/12/2014

Overall study status
Completed

Last Edited
24/06/2021

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hemodialysis is a form of treatment that replicates many of the kidney's functions, filtering the blood to rid the body of harmful waste, extra salt, and water. The aim of this study is to test whether exercise carried out during hemodialysis benefits patients in terms of their general wellbeing and quality of life and also if it benefits physical function and ability to participate in daily activities, like walking and rising from a chair. The effects of participation in the exercise programme on other aspects that may be important to the health of hemodialysis patients (for example, blood pressure) will also be examined. In addition, we will also examine whether this type of additional treatment option is cost effective within the health service setting.

Who can participate?
Adult patients from dialysis units throughout the UK will participate in this study.

What does the study involve?
Once patients have agreed to take part they will complete a series of assessments to measure their quality of life and functional limitations. After this, patients will be allocated to either a usual care haemodialysis plus exercise group or a usual care haemodialysis group. The exercise group will receive the opportunity to exercise during their dialysis for a total duration of 6 months. All patients will be invited to come back for reassessment of quality of life and functional limitations after 6, 9 and 15 months.

What are the possible benefits and risks of participating?
The benefits of undertaking exercise training are that the patients are likely to feel better and healthier, have a potentially improved cardiovascular health, have improved physical, mental and emotional wellbeing, and an improved dialysis efficiency. All participants will have access to additional monitoring not available as part of routine care. For example, fitness and the health

of blood vessels will be assessed. After the study patients will be able to use this information to guide their lifestyle choices, potentially impacting positively upon their health. For patients in the exercise group, there is a very small chance of getting a muscle strain or some joint pain following exercise. Also, blood sugar levels and blood pressure may drop during the exercise, which may make the patient feel sick or dizzy. Rarely, exercise can cause a change to heart function. To reduce the risks of exercise the patients' medical history will be checked to ensure that health risks do not outweigh any benefits.

Where is the study run from?
King's College Hospital, Salford Royal Hospital, Glasgow Western Infirmary, Royal Derby Hospital and Heartlands Hospital (UK).

When is the study starting and how long is it expected to run for?
January 2015 to February 2020

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK).

Who is the main contact?
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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02222402

Secondary identifying numbers
HTA 12/23/09

Study information

Scientific Title
PrEscription of intra-Dialytic exercise to improve quAlity of Life in patients with chronic kidney disease (PEDAL)

Acronym
PEDAL

Study objectives
To determine, in comparison to usual care, whether usual care augmented by intra-dialytic exercise training improves health-related quality of life in stage 5 CKD patients receiving maintenance haemodialysis renal replacement therapy.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/122309
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0006/130659/PRO-12-23-09.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
London – Fulham, 27/11/2014, ref: 14/LO/1851

Study design
Multi-centre pragmatic single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic kidney disease

Interventions
Once patients have agreed to take part they will complete a series of assessments to measure their self-reported QOL and functional limitations. After this, patients will be allocated to either a usual care haemodialysis plus intradialytic exercise group or a usual care haemodialysis group. The exercise group will receive the opportunity to exercise during their dialysis for a total duration of 6 months. All patients will be invited to come back for reassessment of QOL and functional limitations after 6, 9 and 15 months.

Intervention Type
Mixed

Primary outcome measure
A change in Kidney Disease QOL questionnaire Physical Composite Score (KDQOL-PCS) between baseline and 6 months. The KDQOL is a disease-specific quality of life measure.

Secondary outcome measures
Assessed at 6, 9 and 15 months. Change between baseline and follow-up for:
1. KDQOL-PCS
2. KDQOL-MCS
3. KDQOL-Vitality subscale
4. KDQOL- symptom burden subscale
5. IPAQ
6. Height (at screening visit only), weight and anthropometric (BMI, waist to hip ratio)
7. Peak aerobic capacity
8. Duke Activity Status Index (self-report 12-item activity of daily living questionnaire)
9. 10 m Timed-up-and-go (composite test of leg strength, balance, coordination and gait speed)
10. Sit-to-stand 60 (proxy measure of lower extremity muscular endurance)
11. Tinetti Falls Efficacy Scale
12. Habitual physical activity (a self-report assessment via International Physical Activity Questionnaire)
13. Habitual physical activity (GT3X tri-axial accelerometer)
14. Arterial stiffness (via pulse wave velocity and augmentation index)
15. Blood pressure
16. Blood lipid levels – LDL, HDL, triglyceride levels
17. Hb
18. ESAs
19. HBA1c
20. CRP
21. Bicarbonate
22. Phosphate
23. Parathyroid hormone (PTH)
24. Dialysis efficiency

25. Change in medication use (vascular and diabetic medications)
26. EQ-5D, a generic multi-attribute health-related QOL questionnaire for use in cost-utility analysis
27. Health Economic questionnaire regarding resource use
28. All hospitalisations
29. All-cause mortality
30. Cardiovascular mortality
31. Safety/harms (AE, SAE)

Overall study start date
31/07/2014

Completion date
29/02/2020

Eligibility

Key inclusion criteria
1. Prevalent Stage 5 CKD patients (GFR <15 mL/min) receiving maintenance haemodialysis therapy for more than 3 months
2. Male or female
3. Aged >18 years
4. Able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
360

Total final enrolment
380

Key exclusion criteria
1. Patients unlikely to be on HD for > 6 months (this includes cachectic patients, those with severe heart failure, patients in whom dialysis withdrawal is being considered, and patients likely to receive a live-donor transplant or transfer to PD in that period of time)
2. Less than 3 months after the initiation of haemodialysis (patients in this time-frame are generally less clinically stable, many having vascular access procedures performed, and rates of inter-current events, including death and hospitalisation, are very much higher in the first 3 months after commencement of chronic haemodialysis)

3. Deemed to be clinically unstable by treating physician
4. Bilateral lower limb amputees
5. Dementia or severe cognitive impairment (as will be unable to give consent and/or complete questionnaire assessments)
6. Severe psychiatric disorders – except treated stable

Date of first enrolment
01/01/2015

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
King's College Hospital
Denmark Hill
London
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Study participating centre
Salford Royal Hospital
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Study participating centre
Glasgow Western Infirmary
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G11 6NT

Study participating centre

Royal Derby Hospital
Uttoxeter New Road
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DE22 3NE

Study participating centre
Heartlands Hospital
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Sponsor information

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King's College Hospital NHS Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01n0k5m85

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
To be confirmed at a later date

Intention to publish date
01/05/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/09/2020	10/05/2021	Yes	No
Funder report results		01/06/2021	24/06/2021	No	No
HRA research summary			28/06/2023	No	No