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Improving cardiovascular health in dialysis patients using a structured programme of exercise (CYCLE-HD)

Submission date
04/03/2015

Recruitment status
No longer recruiting

Registration date
05/03/2015

Overall study status
Completed

Last Edited
29/07/2024

Condition category
Urological and Genital Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
We are carrying out a study of 130 haemodialysis patients to investigate the effects of 30 minutes of cycling exercise, three times per week during dialysis. Research has shown that exercise outside of a dialysis session can significantly improve fitness and heart function. However, exercise whilst on dialysis has a number of potential effects on the heart and so the long term consequences of this need to be studied. The aim of this study is therefore to monitor the immediate and long term effects of exercise on dialysis on patients heart and quality of life. The study's findings should help to improve the well-being of future haemodialysis patients by making exercise more available on dialysis units in the UK.

Who can participate?
The CYCLE-HD study aims to recruit 130 haemodialysis patients from a number of haemodialysis units across the Leicester Renal Network.

What does the study involve?
This study will investigate the effects of a 6 month programme of exercise during dialysis. Patients who dialyse on certain shifts take part in the exercise programme, and those on other shifts carry on as usual, without exercising to compare. Patients chosen to undertake exercise use a specially designed exercise bike for 30 minutes during routine dialysis sessions. Both of these groups are very important to the research study, as this will allow us to measure the effects of doing exercise in comparison to not doing exercise. The exercise and non-exercise shifts are decided randomly and patients are not be able to choose which group they are in. All the people taking part in both the exercise and the control groups undergo a set of assessments at the beginning and the end of the study. These takes place over one or two days depending on patients preference. Some of these assessments are also done in the middle of the study. They include measuring fitness levels, looking at the structure of the heart and how it well it works, daily levels of activity, height and weight, and some questionnaires.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in this research, although we anticipate that the

exercise training sessions will help participants get fitter. We hope that the results of the study will help us design improved treatments for other kidney patients in the future. Our pilot work has shown no evidence of any side effects or adverse event of doing exercise while on dialysis. The main risk is from the use of adenosine during the cardiac MRI scans as patients can get symptoms similar to that of exercise like mild breathlessness, flushing and palpitations. These are very short lived however and patients can choose not to have the adenosine injection if they wish.

Where is the study run from?
The CYCLE-HD study has been set up by the University of Leicester and University Hospitals of Leicester NHS Trust from where it will run.

When is study starting and how long is it expected to run for?
February 2015 to June 2018

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

Who is the main contact?
Dr James Burton

Contact information

Type(s)
Public

Contact name
Dr James Burton

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CPMS 17951

Study information

Scientific Title
A randomised, cluster controlled trial to investigate the effects of a programme of intradialytic exercise on cardiovascular outcomes in haemodialysis patients.

Acronym
CYCLE-HD

Study objectives
We hypothesise that an intradialytic program of exercise:
1. Leads to a regression in left ventricular mass
2. Is safe with no increase in either cardiac arrhythmias or cardiac fibrosis
3. Leads to an improvement in cardiovascular indices associated with an increased risk and cardiovascular disease and sudden cardiac death.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Northampton, 31/10/2014, ref: 14/EM/1190

Study design
Randomized; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Renal disorders; Subtopic: Renal disorders; Disease: All Renal disorders

Interventions
The study will compare six month of cycling exercise during dialysis (intervention group) against normal dialysis care (no intervention). The intervention group will use specially adapted and calibrated exercise bicycles three times a week during dialysis, aiming for 30 minutes continuous cycling at a level perceived by patients as 'somewhat hard'. This is set on an individual basis after an assessment with a trained member of staff and is then adjusted as required to progress training. Our pilot exercise programme has been well tolerated with no adverse symptoms

reported in any of the exercising patients. It is accessible to patients of different age, gender, culture and ethnicity.

Intervention Type
Behavioural

Primary outcome measure
Reduction in left ventricular mass; Timepoint(s): Measured at baseline and after 6-months of exercise intervention.

Secondary outcome measures
1. Measurements of cardiac structure and function measured using MRI and echocardiography (e.g. left ventricular ejection fraction, blood oxygen delivery)
2. Cardiac rhythm measured using 48 hour ambulatory monitoring
3. Non-invasive cardiac measurements (e.g.blood pressure)
4. Measurements of height, weight, waist circumference and body composition analysis
5. Physical functioning measures including walking and standing tests
6. Objective assessment of habitual physical activity using accelerometry
7. Quality of life and perceived function scores using a variety of validated questionnaires
8. Blood markers of myocardial dysfunction and risk
9. Blood markers of the malnutrition and inflammation

Overall study start date
01/02/2014

Completion date
31/01/2019

Eligibility

Key inclusion criteria
1. Be a prevalent haemodialysis patient (on haemodialysis for more than 3 months)
2. Age 18 years or older
3. Able and willing to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Planned Sample Size: 130; UK Sample Size: 130; Description: To have 80% power to detect a difference between treatment and control groups of a reduction in LV mass of 15g, with an attrition rate of 10%, 65 patients are required in each group.

Total final enrolment
130

Key exclusion criteria
1. Unable to participate in current exercise program due to perceived physical or psychological barriers
2. Unable to undergo MRI scanning (metal implants / prostheses, claustrophobia etc.)
3. Unfit to undertake exercise according to the American College of Sports Medicine guidelines
4. Contraindications to exercise testing (35) that include:
4.1. Recent significant change in resting ECG that suggests significant ischaemia, recent myocardial infarction (2 weeks) or other acute cardiac event;
4.2. Unstable angina;
4.3. Uncontrolled cardiac dysrhythmias causing symptoms or haemodynamic compromise;
4.4. Symptomatic severe aortic stenosis
4.5. Uncontrolled symptomatic heart failure
4.6. Acute pulmonary embolus or pulmonary infarction
4.7. Acute myocarditis or pericarditis
4.8. Suspected or known dissecting aneurysm
4.9. Acute systemic infection, accompanied by fever, body aches or swollen lymph glands
5. Age <18 years
6. Unable or unwilling to give informed consent

Date of first enrolment
16/03/2015

Date of final enrolment
07/03/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leicester
Department of Infection, Immunity and Inflammation
Maurice Shock Medical Sciences Building
University Road
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United Kingdom
LE1 9HN

Sponsor information

Organisation
University of Leicester (UK)

Sponsor details
Gwendolen Road
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England
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LE5 4PW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04h699437

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

Methodology data, including reproducibility of imaging techniques, as will the data on cardiac rhythm will be published within the first 18 months. Baseline cross-sectional data, including cardiac and physical function, will be published around 6 months after recruitment has closed. We anticipate publication of the primary outcome data within 12 months of the end of the trial.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
Deidentified individual participant data collected for the study, and a data dictionary defining each field in the set, will be made available to others on specific to request to the chief investigator (Prof. James Burton [dsm12@le.ac.uk]) provided all regulatory and data sharing approvals are obtained after. This request should include a pre-specified analysis plan. These data will be available after publication of the primary study findings. There is no time limit for such requests.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/07/2016		Yes	No
Basic results		20/01/2020	20/01/2020	No	No
Protocol file	version V4	27/06/2016	17/12/2020	No	No
Results article	Effects on left ventricular mass	01/06/2021	04/05/2021	Yes	No
Results article	Effect of cycling on microparticles or circulating markers of systemic inflammation	02/12/2021	03/12/2021	Yes	No
Other publications	Feasibility substudy in frail patients	03/11/2020	25/07/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Cost-effective analysis	08/04/2021	08/04/2024	Yes	No
Other publications	Defining myocardial fibrosis in haemodialysis patients with non-contrast cardiac magnetic resonance	13/07/2018	08/04/2024	Yes	No
Other publications	The cardiovascular determinants of physical function in patients with end-stage kidney disease on haemodialysis	30/11/2020	08/04/2024	Yes	No
Other publications	The reliability and feasibility of non-contrast adenosine stress cardiovascular magnetic resonance T1 mapping in patients on haemodialysis	08/06/2020	08/04/2024	Yes	No
Other publications	Impact of physical activity on surrogate markers of cardiovascular disease	28/06/2024	29/07/2024	Yes	No