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Cardiovascular risk and physical condition in kidney patients

Submission date	Recruitment status	[_] Prospectively registered
27/10/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/01/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/09/2019	Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
People with kidney problems often suffer from poor quality of life and many health problems. For example, kidney disease patients are more likely to develop heart disease, and many of them find that their muscles become weak and they feel very tired. Having a kidney transplant can transform the life of someone whose kidneys have failed through disease. However, the new kidney does not usually work as well as those of a healthy person and transplant patients can still suffer from a variety of health problems. They also have to take drugs to prevent their immune system rejecting the new kidney, which can cause side effects. We all know that exercise is good for us. In healthy people it improves the health of the heart and strengthens the muscles. Therefore, exercise might be able to help people with kidney disease too, but there has not yet been much research to study this. Before we carry out research to see how exercise might benefit kidney patients, we first need to find out about their current activity levels, their physical fitness, and how this relates to any health problems they might have. We also need to compare them to healthy people to assess what effects the kidney problem is having.

Who can participate?
People aged over 18 with kidney disease and healthy people of the same age and sex

What does the study involve?
Participants are invited to the hospital for a series of tests to measure their fitness, their heart health and how much body fat and muscle they have. They are asked to fill in some questionnaires about their quality of life and their health problems and symptoms, and we will give them a small activity monitor to wear for a week to measure how active they are.

What are the possible benefits and risks of participating?
The results of this study will give us important new information which will help us design exercise programmes suitable for the needs of kidney patients. In the future we will do more research to test how these exercise programmes might help people with kidney disease to enjoy a more active and healthy lifestyle. There are limited risks in taking part in this study. Blood samples taken during the study may cause slight discomfort or pain and bruising to the arm afterwards. Further, these blood tests are taken in a “fasted” state (i.e. no food or drink (apart from water) since the previous evening). Participant’s body composition in the study is assessed

using a DEXA scan, a type of X-ray. A DEXA scan involves a low dose of radiation, but the dose is small and equal to about 10 days of normal background radiation. The functional tests performed in the study (i.e. shuttle walk tests, sit to stand tests) are associated with a low risk of accident or injury (as with all physical activity). However, these tests have been routinely used by our group and are well tolerated in kidney patients. All tests will be carried out by trained researchers in a hospital setting with resuscitation facilities available. Overall, the main disadvantage of taking part is the time commitment involved in the hospital visits for assessments (2 or 3 visits in total), although travel expenses and car parking will be reimbursed. Whilst straightforward to answer, the pack of questionnaires participants are required to fill in can take upwards of 1 hour to complete

Where is the study run from?
Leicester General Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2014 to January 2018

Who is funding the study?
Private Charitable Trust

Who is the main contact?
Prof. Alice Smith
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
14/EM/1049

Study information

Scientific Title
COCO: CardiOvascular risk factors and physical COndition in kidney patients

Acronym
COCO

Study objectives
An exploratory observational study designed to collect data to inform the subsequent design of a realistic and effective exercise programme suited to the needs of this population, and research studies to evaluate its ability to positively impact upon important health issues in kidney patients. It is based at University Hospitals of Leicester.

We hypothesise that low levels of physical activity and physical functioning are associated with unfavourable body composition (lower muscle mass and higher fat mass), increased cardiovascular risk, and poorer quality of life in kidney patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Research Ethics Committee East Midlands (Derby), 21/07/2014, ref: 14/EM/1049

Study design
Observational cross-sectional study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Established chronic kidney disease (all stages are eligible including those on dialysis or with an established kidney transplant)

Interventions
This project will use a combination of subjective and objective measures to explore exercise capacity and habitual physical activity levels in kidney patients and healthy controls, and will additionally collect data on clinical parameters, body composition, cardiovascular risk, central haemodynamics and quality of life. This is an exploratory observational study designed to collect data to inform the subsequent design of a realistic and effective exercise programme suited to the needs of this population, and research studies to evaluate its ability to positively impact upon important health issues in kidney patients.

Intervention Type
Other

Primary outcome(s)

1. Physical function: Incremental Shuttle Walking Test (ISWT) and Endurance Shuttle Walking Test (ESWT), Sit-to-stand-5 (STS-5), and STS-60
2. Body composition: anthropometric measures, Bioelectrical Impendence Analysis (BIA), and dual-energy X-ray absorptiometry (DEXA)
3. CVD risk factors: pulse wave velocity, Non-Invasive Cardiac Outcome Measures (NICOM), and systemic inflammatory status
4. Venepuncture for inflammatory and other cardiovascular risk markers
5. General Questionnaires:
5.1. Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue
5.2. Fatigue scales
5.3. European Quality of Life-5 Dimensions (EQ5D)
6. Population-Specific Questionnaires:
6.1. Transplant patients:
Kidney Transplant Questionnaire (KTQ)
6.1.1. Leicester Kidney Patient Physical Activity Questionnaire Tx (LKP-PAQ Tx)
6.1.2. Renal Patient Outcome Scale (POS-S Renal plus transplant-specific questions)
6.1.3. Dialysis Patients : Leicester Kidney Patient Physical Activity Questionnaire (LKP-PAQ)
6.1.4. Renal Patient Outcome Scale (POS-S Renal)
6.1.5. Early/Predialysis CKD: Leicester Kidney Patient Physical Activity Questionnaire (LKP-PAQ)
6.1.6. Leicester Kidney Symptom Questionnaire (LKSQ)
6.2. Healthy controls:
6.2.1. Leicester Kidney Patient Physical Activity Questionnaire (LKP-PAQ)
6.2.2. Leicester Kidney Symptom Questionnaire (LKSQ)
7. Habitual physical activity and nutritional intake: accelerometers worn for seven days; food diary completed for 7 days
8. Clinical parameters: (urine sample and fasted blood test). For kidney patients only, co-morbidities and medication details will be extracted from medical records by researchers after visits completed.

Note: This is an exploratory observational study investigating relationships between physical activity and functioning, body composition, cardiovascular risk markers and QoL. There is no single primary outcome.

Outcome measures measured at a single time point only (cross-sectional study).

Key secondary outcome(s))
1. Evaluation of the accuracy of BIA vs DEXA in renal transplant patients
2. Evaluation of the accuracy of the self-reported LKP-PAQ questionnaires versus objectively measured physical activity and functioning tests

Completion date
31/01/2018

Eligibility

Key inclusion criteria
1. Patients with established chronic kidney disease (all stages are eligible including those on dialysis or with an established kidney transplant)
2. Healthy control participants

Participant type(s)

Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
106

Key exclusion criteria
1. Age <18 years
2. Pregnancy
3. Any element of study assessment protocol considered by own clinician to be contraindicated due to physical impairment, comorbidity or any other reason
4. Visual or hearing impairment or insufficient command of English to give informed consent or comply with the assessment protocol
5. Inability to give informed consent for any reason

Date of first enrolment
23/09/2014

Date of final enrolment
02/08/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leicester General Hospital
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation

University Hospitals of Leicester NHS Trust

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Charity

Funder Name
Self-funded. This is a single-centre study funded by a £1.5m grant awarded to Dr Alice Smith by an anonymous private charitable trust

Results and Publications

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	results	01/08/2019	10/09/2019	Yes	No
Results article	results	01/08/2019	10/09/2019	Yes	No
Results article	results	01/01/2019	10/09/2019	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes