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Physical activity, immune function and inflammation in kidney patients - a pilot study

Submission date
27/10/2015

Recruitment status
No longer recruiting

Registration date
22/01/2016

Overall study status
Completed

Last Edited
15/02/2023

Condition category
Urological and Genital Diseases

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

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 infections, 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. It is well known 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. Having kidney disease affects the cells in the blood which control the immune system. Some of these cells don't work well, so the body can't fight infection properly. On the other hand, some of the immune cells become overactive and can damage the inside of the blood vessels – this is one of the important causes of heart disease in kidney patients. Exercise also affects the same cells in the blood. In healthy people the effects of regular moderate exercise tend to improve immune function and reduce the risk of heart disease. However, it cannot be assumed that exercise will have the same effect on the blood cells in people with kidney disease because the kidney disease itself also affects the blood cells. It is not yet known how the combination of exercise and kidney disease will affect the blood cells, but this needs to be understood so that kidney patients can be advised about the best exercise to do.

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 asked to do a 20-minute exercise session of brisk walking and blood samples are taken before and after the exercise. The blood cells are studied to see what effect the exercise has on them in healthy people and kidney patients.

What are the possible benefits and risks of participating?
The results of this study will provide important new information which will help to design

exercise programmes suitable for the needs of kidney patients. In the future more research will be done to test how these exercise programmes might help people with kidney disease to enjoy a more active and healthy lifestyle. In this study a total of 60 ml of blood is collected from each participant. As is always the case when collecting blood samples, there is a small risk of pain and bruising. To minimise these risks they will be performed by a trained member of the research team. Shuttle walk tests are associated with a low risk of accidental injury (as with all physical activity). These tests are frequently used by the Leicester Kidney Exercise Team for other research studies involving kidney patients at all stages of their disease and are well-tolerated. Over 100 tests have been carried out by the researchers without any problems or injuries. All tests will be carried out by trained researchers in a hospital setting with resuscitation facilities available.

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 2015 to September 2020

Who is funding the study?
Private Charitable Trust

Who is the main contact?
Dr Alice Smith
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15/EM/0391

Study information

Scientific Title
Physical activity, immune function and inflammation in kidney patients - a pilot study

Acronym
PINK

Study objectives
The PINK study is an exploratory study investigating the effects of a single 20-minute bout of standardised walking exercise on circulating immune and inflammatory cells and factors. This is intended to provide preliminary information to generate hypotheses for subsequent more focussed studies of this topic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Research Ethics Committee East Midlands (Derby), 18/09/2015, ref: 15/EM.0391

Study design
Single-centre interventional trial

Primary study design
Interventional

Secondary study design
Pre-post study

Study setting(s)
Hospital

Study type(s)
Other

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
Chronic kidney disease

Interventions

The study will comprise of two visits. The first visit will be a familiarisation visit. This will involve and incremental shuttle walk test to determine the speed at which the endurance shuttle walk test will be completed. The endurance shuttle walk test will then be completed, in order to ensure that the patient is able to complete the full 20 minutes. Anthropometric data, information on cardiac function and activity level will also be taken on this visit.

The second visit will comprise of a venous blood sample, completion of the endurance shuttle walk test at the speed determined in visit 1, another venous blood sample post-exercise, and a final venous blood sample 60 minutes post exercise.

Intervention Type
Behavioural

Primary outcome measure
Blood samples will be analysed for:
1. Markers of metabolism, cardiovascular risk, inflammation, oxidative stress, endothelial activation and immune function in plasma serum
2. Analysis of immune and inflammatory cell populations by flow cytometry
3. Expression of mRNA by RT-PCR

These will be measured from blood samples taken pre exercise, 5-10 minutes post exercise and 60 minutes post exercise.

Secondary outcome measures
1. Anthropometric measures (height, weight, hip circumference)
2. Body composition by bioelectrical impedance analysis
3. Cardiac bioreactance by NICOM (non-invasive cardiac output monitoring)
4. Time spent in leisure activities (Leisure Time Exercise Questionnaire)

These measures will be made once during the familiarisation visit (Visit 1). Clinical information will be obtained from medical records .

Overall study start date
24/09/2015

Completion date
01/09/2020

Eligibility

Key inclusion criteria
1. Kidney patients of both genders aged 18 or over, with established chronic kidney disease including those on renal replacement therapy or with a transplant
2. Matched healthy controls

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
6 per condition (12 total)

Key exclusion criteria
1. Aged under 18 years
2. Pregnancy
3. Received kidney transplant less than 6 months prior to study entry
4. Any element of study assessment protocol considered by own clinician to be contraindicated due to physical impairment, co-morbidity or any other reason
5. Inability to give informed consent for any reason
6. Visual or hearing impairment or insufficient command of English to give informed consent or comply with the assessment protocol

Date of first enrolment
26/10/2015

Date of final enrolment
31/08/2020

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
University Hospitals of Leicester

Sponsor details

Leicester General Hospital
Gwendolen Road
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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
The results of the research are expected to become available from 2017. The results will be publicised in posters and leaflets in clinical areas around the hospital, and a report will be written in our Kidney Research Newsletter. Also, the results will be published in a medical journal.

Intention to publish date
01/09/2021

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/05/2017		Yes	No

Other publications	Sub-study results	30/06/2018	15/02/2023	Yes	No
Results article		01/01/2020	15/02/2023	Yes	No