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A trial to investigate how newly-discovered factors in the blood may affect the health and wellbeing of people with kidney disease

Submission date
04/04/2018

Recruitment status
No longer recruiting

Registration date
02/05/2018

Overall study status
Ongoing

Last Edited
18/09/2023

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Chronic Kidney Disease (CKD) affects how the body functions in many different ways and can cause problems with the heart and blood vessels, the immune system, the bones and the muscles. Many people with kidney disease suffer from troublesome symptoms and feel tired and weak which can make normal daily activities more difficult. We are carrying out a programme of research to better understand what causes these problems and to find ways that kidney patients can improve their own health and wellbeing by adjustments to their lifestyle.
In our research studies we investigate the role of various genes, cells and factors in the blood which may be involved in kidney disease. Genes are made from a chemical called DNA in your cells, which you inherit from your parents. We all have numerous small variations in our DNA which can affect how the body works.
Some of the factors, cells and genes that we are investigating in our other studies are newly discovered and we do not know enough about them to fully understand our findings. We need to study them in more detail, for example :
• How the cells and factors change over time
• How the genes, cells and factors are related to one another
• How the genes, cells and factors are related to the long term health of kidney patients
• How the genes, cells and factors differ between individual kidney patients (to help us tailor future treatments to the patients who will benefit the most)
• How the genes, cells and factors differ in kidney patients and healthy people

This study investigates these genes, cells and factors in people with kidney disease and healthy people of the same age, gender and ethnic background. The results will help us in our future research to find ways to benefit the health and wellbeing of kidney patients.

Who can participate?
1. Adults aged 18 years or above with chronic kidney disease
2. Healthy volunteers aged 18 years or above

What does the study involve?
Participants are assessed at the start of the study, and five more times over a 36 month period. They have a blood sample and urine sample taken at each assessment, as well as human body measurements such as height, weight and fat mass. Clinical records are accessed and assessed for up to five years after their last visit to gather data on the progression of the disease and outcomes.

What are the possible benefits and risks of participating?
There are no direct benefits for those taking part. As for all blood samples, there is a small risk of mild discomfort and bruising, but this is not dangerous. The measurements are all easy, safe and comfortable and should not cause any problems. The main disadvantage is the time taken to visit the hospital for the blood samples and measurements, as each visit takes up to 1 hour.

Where is the study run from?
University Hospitals of Leicester NHS Trust (UK)

When is the study starting and how long is it expected to run for?
January 2018 to December 2026

Who is funding the study?
Anonymous Private Charitable Trust

Who is the main contact?
Prof Alice Smith (Public)

Contact information

Type(s)
Public

Contact name
Prof Alice C Smith

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Additional identifiers

Integrated Research Application System (IRAS)
240492

Protocol serial number
MAP-KD Protocol version 1 dated 11th December 2018

Study information

Scientific Title
MetAbolic, Immunological and Pathological Factors in Kidney Disease

Acronym
MAP-KD

Study objectives
MAP-KD aims to establish associations between novel circulating factors with kidney disease progress and clinical outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Derby Research Ethics Committee, 03/04/2018, ref: 18/EM/0031

Primary study design
Observational

Study design
Prospective observational study

Study type(s)
Quality of life

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

Interventions
This study recruits Chronic Kidney Disease (CKD) and non-CKD healthy controls, and involves up to a total of six assessment visits over a 36 month period.
30ml of venous blood is collected at baseline (visit 1), and up to a total of 6 times over a 36 month period. Plasma, serum, and peripheral blood mononuclear cells (PBMCs) are separated and stored at -80°C for later analysis including but not exclusive to microRNAs, proteomics, metabolomics, and genetic factors involved in disease progression and development of co-morbidities.
For non-CKD controls and CKD participants where blood sampling takes place on a scheduled visit to the research unit (i.e. when no routine clinical blood samples will be analysed) a further 5ml sample is taken to be analysed by pathology lab for markers of renal disease and co-morbidities (renal profile, iron status, plus metabolic, oxidative stress, pro/anti-inflammatory status markers).

Anthropometric and functional outcomes are performed on the same visit as the blood samples are obtained up to a total of 6 over a 36 month period, and are used to characterise participants.

Participant’s clinical records are also accessed annually for up to 5 years following their final visit to gather data on health service usage, disease progression, and clinical outcome.

Intervention Type
Not Specified

Primary outcome(s)
Circulating markers of oxidative stress, pro/anti-inflammatory status, immune parameters and relevant genotyping are measured from a blood sample at entry and up to 5 further timepoints in a 36 month period

Key secondary outcome(s)
1. Muscle and fat mass are measured using Bioelectrical Impedance Analysis at entry and up to 5 further timepoints in a 36 month period
2. Height, weight, waist and hip circumference are measured at entry and up to 5 further timepoints in a 36 month period
3. Clinical parameters (such as medications, blood and urine test results, co-morbidities, outcomes and healthcare usage) are extracted from medical records throughout the study
4. Blood markers of renal disease and co-morbidities (CVD risk, metabolic and immune function) are measured from a blood sample at entry and up to 5 further timepoints in a 36 month period
5. Urine markers of renal disease and co-morbidities (oxidative stress, microRNA expr35090ession, markers of muscle mass) are measured from a urine sample at entry and up to 5 further timepoints in a 36 month period
6. Muscle size is measured using ultrasound and muscle quality is measured using myotonometry at entry and up to 5 further timepoints in a 36 month period
7. Physical functioning is measured using the Duke Activity Status Index (DASI) at entry and up to 5 further timepoints in a 36 month period
8. CKD symptoms are measured using the Kidney Symptom Questionnaire (KSQ) at entry and up to 5 further timepoints in a 36 month period

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Kidney disease patient:
1. Established CKD according to these guidelines : http://www.gpnotebook.co.uk/simplepage.cfm?ID=x20140903131721906919
or identified with the IMPAKT tool : http://www.impakt.org.uk/HOME-459.html
2. Willing and able to give informed consent and comply with the study protocol
3. Male or female
4. Aged 18 years or above

Healthy control:
1. Willing and able to give informed consent and comply with the study protocol.
2. Male or female
3. Aged 18 years or above.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
38

Key exclusion criteria
Both kidney disease patients and healthy controls:
1. Age <18 years
2. Any other significant disease or disorder which, in the opinion of the patient's own clinician, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant's ability to participate in the study.
3. Inability to give informed consent or comply with the protocol for any reason.

Date of first enrolment
01/04/2018

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals of Leicester NHS Trust
United Kingdom
LE5 4PW

Sponsor information

Organisation

University Hospitals of Leicester NHS Trust

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Other

Funder Name
Private Charitable Trust

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Alice C Smith, alice.smith@le.ac.uk

Additional documentation is also available on request from the Chief Investigator Professor Alice C Smith, alice.smith@le.ac.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/04/2022	18/09/2023	Yes	No
Results article			18/09/2023	Yes	No
Results article		14/01/2022	18/09/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet		30/04/2018	01/04/2019	No	Yes
Participant information sheet		30/04/2018	01/04/2019	No	Yes
Plain English results		18/09/2023	18/09/2023	No	Yes