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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

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

### ORCID ID
http://orcid.org/0000-0002-9234-9060

### Contact details
Kidney Lifestyle Team, Academic Unit
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# Additional identifiers

### EudraCT/CTIS number
Nil known

**IRAS number**
240492

**ClinicalTrials.gov number**
Nil known

**Secondary identifying numbers**
MAP-KD Protocol version 1 dated 11th December 2018, IRAS 240492

# Study information

**Scientific Title**
MetAbolic, Immunological and Pathological Factors in Kidney Disease

**Acronym**
MAP-KD

**Study hypothesis**
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

**Study design**
Prospective observational study

**Primary study design**
Observational

**Secondary study design**
Longitudinal study

**Study setting(s)**
Hospital

**Study type(s)**
Quality of life

**Participant information sheet**
See study outputs table

**Condition**
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 measure
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

## Secondary outcome measures
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

## Overall study start date
01/01/2018

## Overall study end date
31/12/2026

# Eligibility

### Participant 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
50

### Total final enrolment
38

### Participant 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.

### Recruitment start date
01/04/2018

### Recruitment end date
31/03/2023

# Locations

### Countries of recruitment
England

United Kingdom

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

## Sponsor information

### Organisation
University Hospitals of Leicester NHS Trust

### Sponsor details
Leicester General Hospital
Leicester
England
United Kingdom
LE5 4PW

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/02fha3693

## Funder(s)

### Funder type
Other

### Funder Name
Private Charitable Trust

## Results and Publications

### Publication and dissemination plan

Planned dissemination of the results at scientific and medical conferences, via platforms associated with the NIHR Leicester Biomedical Research Centre and the Leicester Precision Medicine Institute, and patient and public forums, social media etc.
Planned publication of the results in scientific and medical journals.

## Intention to publish date
01/04/2022

## 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? |
|---|---|---|---|---|---|
| Participant information sheet | | 30/04/2018 | 01/04/2019 | No | Yes |
| Participant information sheet | | 30/04/2018 | 01/04/2019 | No | Yes |
| HRA research summary | | | 28/06/2023 | No | No |
| Plain English results | | 18/09/2023 | 18/09/2023 | No | Yes |
| 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 |