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MetAbolic, Immunological and Pathological Factors in Kidney Disease (MAP-KD)

IRAS 240492

Control Participant Information Sheet

Version 3 : 20th March 2018

You are invited to take part in a research study. Before you decide, it is important that you fully understand what the study involves and why it is being done. Please read the following document carefully and discuss it with others if you wish. If there is anything that is unclear or you would like more information on, please ask one of us.

What is the purpose of this study?

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 people who do not have kidney disease

The MAP-KD study will investigate these genes, cells and factors in people with kidney disease and people of the same age, gender and ethnic background who do not have kidney disease. The results will help us in our future research to find ways to benefit the health and wellbeing of kidney patients.

Why have I been invited?

We are asking you to take part as a Control Participant because you **do not** have Chronic Kidney Disease. We are doing this research so we can understand better how genes, cells and factors in the blood are involved in the processes which can damage the health of kidney patients and how we might be able to improve this in the future.

Do I have to take part?

It is up to you whether you decide to participate or not. If you decide to take part then you will be given this Information Sheet and asked to sign a consent form. You will be free to stop participating at any time and without giving a reason.

What will happen if I take part?

During the study, we ask you to continue your life in the usual way. You should follow your usual diet, and take any medicines as prescribed.

If you decide to take part you will be asked to attend the hospital for a research visit. After this first visit, you may be asked to attend again for up to a maximum of 6 visits over 3 years. However, these additional visits are optional and will be discussed with you at the first visit.

At the first visit we will go through this information sheet again with you and answer any questions you might have. If you are still happy to participate we will ask you to sign the consent form, and you will be given a copy to keep.

Each research visit involves :

- A blood sample (30ml which is about 2 tablespoons), taken from your arm. A small part of this blood sample will be sent to the hospital pathology lab to check your kidney function (unless this has previously been checked in the last three months). In the unlikely event that we find anything that means you would not be suitable to participate in this study, you and your GP would be informed;

- A urine sample

Each research visit may also include some or all of the following :

- Measurements of your height, weight and body composition (how much fat and muscle you have) (10 minutes)
- Measurements of the size and quality of your arm and leg muscles (10 minutes)
- Measurements of your walking speed, ability to get up from a chair, walk and sit down again, and how many times you can rise from a chair in 1 minute (10 minutes)
- Some questionnaires (15 minutes). You can take these home with you to fill in and send back to us later

Details of these measurements are described in the Appendix at the end of this Information Sheet. We will discuss with you and decide together how many of the measurements we will take. If you do all of them the visit will take about 1 hour, but the visit will be shorter if we only do some of the measurements.

We will also discuss with you whether you are willing to come back again for optional future research visits. These will involve the same blood sample and measurements as your first visit. If you agree to future visits, we will choose convenient dates with you. You can change your mind about the additional visits at any time without giving us a reason.

What are the possible disadvantages and risks of 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 you any problems.

The main disadvantage is the time taken to visit the hospital for the blood samples and measurements. Each visit will take about 1 hour if you do all the measurements.

We will reimburse your travel, parking and any other expenses.

What are the potential benefits?

There are no direct benefits to taking part in this research. However, the results will be extremely useful to help us understand why patients with kidney disease can suffer from a variety of health problems and symptoms. You will also receive an accurate assessment of your body composition.

What happens when the research study stops?

After the study you will continue with your usual activities and lifestyle. If you are receiving any other clinical care this will not be affected.

What if something goes wrong?

In the very unlikely event of you being harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you.

If you wish to make a complaint about the study you can contact the UHL Patient Information and Liaison Service by writing to PILS, Gwendolen House, Gwendolen Road, Leicester LE5 4QF, or telephoning 08081 788337 (free phone number).

Confidentiality

All information that is collected about will be kept strictly confidential. Any information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it. The blood sample that we will collect from you will be labelled with a code, not your name or any other identifiable information. The decode list will be stored securely by the Chief Investigator (Professor Alice Smith) in a locked filing cabinet at the University Hospitals of Leicester NHS Trust and no one else will have access to it.

In the unlikely event of your blood tests showing any unexpected results, we will ask for your permission to notify your own GP.

What will happen to the samples taken during this study?

The samples taken during this study will be stored at the University Hospitals of Leicester or the University of Leicester where they will be analysed in our research laboratory. All samples will be labelled with an anonymous code so it is not possible to identify the participant.

We will use the samples to study genes, cells and factors in the blood that may be relevant to kidney disease. This will help us to understand better the results of our other studies which test ways of improving the health and wellbeing of kidney patients through lifestyle management. The results will also help us to tailor future treatments to individual patients who may benefit the most.

We may transfer the samples to an approved research laboratory at another organisation that we have a collaborative agreement with to carry out some of the analyses. All samples and information transported elsewhere will be labelled with an anonymous code and it will not be possible to identify you .

If there are any remaining samples after the end of this study we would like to store them in a research storage bank or use them in studies that obtain ethical approval in the future, to further investigate the causes and effects of kidney disease and how lifestyle could be used to improve health and wellbeing. If you would prefer for your samples not to be used in future studies you can indicate this on the Consent Form and any remaining samples will be destroyed after MAP-KD has finished.

What will happen to the results of this study?

We hope to publicise the results (all anonymised) of this study in medical journals and on posters and during conference presentations. If you would like us to send you a report of this study please send researcher an email and we will be more than happy to send one to you.

We will store the research data and results for 5 years after the end of the study.

Who is organising and funding the research?

The research is being organised by the Leicester Lifestyle Team at the John Walls Renal Unit, Leicester General Hospital and is led by Professor Alice Smith. The study is funded by Kidney Research UK.

Any research that involves NHS patients or staff, information from NHS medical records or uses NHS premises or facilities must be reviewed by an NHS Research Ethics Committee before it can go ahead. This study has been reviewed by the NHS Research Ethics Committee East Midlands – Derby. A favourable opinion means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to make an informed decision.

Contact and Further Information:

If you would like any further information about this study please contact the Chief Investigator Professor Alice Smith.

Professor Alice Smith
Leicester Kidney Exercise Team,
UoL Academic Unit
Leicester General Hospital, LE5 4PW.
Tel 0116 258 4346
Email kidney.exercise@uhl-tr.nhs.uk

Thank you for reading this Information Sheet, and for considering taking part in this study.
You will be given a copy of this information sheet and signed consent form to keep

Appendix

Details of Measurements

Blood sample

We will take a blood sample from your arm at every visit. A small part of this blood sample will be sent to the hospital pathology lab to check your kidney function (unless this has previously been checked in the last three months). In the unlikely event that we find anything that means you are not be suitable to participate in the MAP-KD study as a Control Participant, you and your GP will be informed.

The rest of the blood sample will be stored in the research labs and analysed for cells, genes and factors relevant to our research into improving the health and wellbeing of people with kidney disease.

As part of the lab analysis we will extract the genes from some of your blood cells to analyse the DNA. This means that we will look for small variations that you have inherited from your parents. Sometimes these small DNA variations make a difference to the way your body works in certain situations. Looking at these variations will help us to understand why some people develop health problems or experience certain symptoms. We will not analyse any DNA that could be used to diagnose disease.

Urine sample

We will give you a pot to collect a sample of your urine when you go the toilet during your visit

We may also carry out some or all of the following measurements :

Height, weight and circumferences

We will weigh you and measure your height using standard scales, and measure your waist and hip circumference using a measuring tape.

Body composition

We have two different machines which measure how much fat and muscle you have. We will use one of these different machines, depending on which is most convenient on the day.

Bioelectrical Impedance Analysis (BIA)

The BIA is a bit like a normal weighing scale but it also has handles for you to hold. You stand on the platform in bare feet and take a firm grip on the handles. The machine then takes a measurement of your body composition. The test takes about 2 minutes.

Body Composition Monitor (BCM)

The BCM is a more portable device than the BIA. You lie comfortably on a couch and we attach small electrodes to your hand and foot. The machine then takes a measurement, which takes about 2 minutes.

Muscle ultrasound

We will use ultrasound to measure the size of muscles in your arms and legs. The images also show us the quality of your muscle.

This is a painless procedure that takes about 10 minutes. You will lie down on a couch and a researcher will apply some jelly to the muscle area and then pass the probe across the area to take the measurement.

Myotonometery test

Following the ultrasound scan and whilst you are still lying down, we will apply a small probe to your arm and leg muscle. The probe has a small tip (about the size of ballpoint pen tip) which will lightly push into your muscle (it does not go through the skin). This measures the vibration in your muscle caused by this short ‘push’ and tell us about the quality of the muscle. This is completely painless and the ‘push’ from the probe tip lasts less than 1 second. We will take 3 readings.

Gait speed test

To measure speed you usually walk, we will ask you to walk 4 metres at your normal walking pace. We will time you using special sensors than will make a noise when you walk past them. This test takes a few minutes to complete.

Timed up-and-go test

To measure your balance, strength, agility, we will ask you to stand up from a chair, walk as quickly as you can around a cone, and then sit back down again. This test takes a few minutes to complete. You can practice a couple of times before the actual test so you know exactly what to do.

Sit-to-Stand Test

The sit-to-stand test measures how easily you can stand up from a chair without using your hands. After some practice goes at it, we will measure how many times you can do this in 1 minute.

Questionnaires (Survey pack)

We will ask you to fill in the MAP-KD Survey Pack, which consists of 4 short sections and takes about 15 minutes to complete. You can do this during your visit or take it home with you to fill in later. If you take it home we will give you a pre-paid envelope to return it to us.

Section 1: About You

Some questions about you

Section 2: Questionnaires

A: Duke Activity Status Index (DASI)

About your ability to carry out day-to-day activities

B : GP Physical Activity Questionnaire (GP-PAQ)

About your daily activity levels

C: **Symptom Questionnaire**

About the symptoms you experience

D : SF-12 Health Survey

About how your health affects your quality of life

Section 3 : Your comments and further information

For you to tell us anything else you would like to about issues raised in the questionnaires or the study

Section 4 : Contact Form

An optional section for you to give us your contact details if you would like to find out more about our research work.