TO BE PRINTED ON LOCAL TRUST HEADED PAPER

The Kidney Test Study

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# Invitation to join a research study

# What is this study for?

Many people have a drop in how well their kidneys work, particularly as they get older. Checking for this is important.

We test people’s kidney function with a simple blood test. The NHS does this millions of times every year. It gives an estimate of how well the kidneys work.

We can analyse this simple blood test in different ways. We are not sure which way gives the best estimate. We hope this study will help us find out.

# Do I have to take part?

No. Taking part is your choice. No one will think badly of you if you don’t take part. You can withdraw at any time if you choose to take part.

# What are the possible risks?

There is very low risk in this study. Some people have an allergic reaction to iodine, which is in the injection we use. This is rare and your nurse will ask you about it.

# Will I be paid for taking part?

No. We will pay travel and parking costs for extra hospital visits for the study.

# Can I see an all-female research team?

Yes. If as a woman you prefer this, we can arrange for you to be seen by only female research nurses.

# What will happen to me if I take part?

You will have 7 hospital visits in 3 years:

| First visit |
| --- |
| This takes around 5 hours but we will keep you as comfortable as we can and provide refreshments.  We will weigh and measure you. Then we will take some blood samples and a urine sample.  Next you will have a kidney test. The nurse will give you an injection in your arm. Then, over the next 4 hours, the nurse will take 4 more blood samples. This tests how quickly your kidneys clear the injection from your blood. |

| Five short visits |
| --- |
| You will then have 5 short visits, 1 every 6 months. They take about 10 minutes. We will try to fit these in with routine appointments where we can. We will take a blood sample and a urine sample at these visits. |

| Final visit |
| --- |
| Your final visit will be in 3 years. It will be the same as the first visit. Then you will leave the study. |

# Where can I get more information?

The rest of this leaflet has the full details. Please read on if you are interested!

For questions about the study please contact:

<Insert local contact name and telephone number>

Participant Invitation and Information Sheet

# Study Title

The eGFR-C study:

Accuracy of glomerular filtration rate (GFR) estimation using creatinine and cystatin C and albuminuria for monitoring disease progression in patients with stage 3 chronic kidney disease

**Invitation to take part in a research study to improve the way kidney disease is identified and measured**

Thank you for reading this information sheet about our research study: we would like to invite you to take part.

Before you decide whether or not you want to join we would like you to understand why the research is being done and what it would involve for you. Please consider the following information carefully and discuss it with others and your doctor if you wish. Do feel free to ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1 tells you why we are doing this study and what will happen if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Part 1

# What is the purpose of the study?

Kidney disease is common, affecting approximately 1 in 10 people. Early diagnosis is important, as is checking whether your disease is worsening. Part of both diagnosis and monitoring of disease is assessment of kidney function by a blood test and measurement of kidney protein leak by a urine test. The most accurate measurement of kidney function can be obtained by something called measured glomerular filtration rate (mGFR). However this test is not used in routine medical care as it requires several hours to perform; therefore GFR is currently estimated (eGFR) from a simple laboratory test on blood. This eGFR test is carried out every time you are seen about your kidney function and the change in eGFR with time is used by doctors to assess if your kidney function is stable, improving or getting worse. However, we do not fully understand if eGFR properly reflects changes in kidney function within individuals and across different ethnic and patient groups. This is a very important question, because understanding how to best provide this test may help us to improve care for people with kidney disease.

This research project is designed to assess an eGFR test that may improve measurement of kidney function and hence enable more precise identification of kidney disease and monitoring of kidney function. Knowledge of kidney function is also helpful in maintaining the correct dose of medicines that you may be prescribed and early identification of kidney disease may allow treatment to prevent worsening of kidney function. The study is being conducted by kidney specialists and general practitioners in several major centres across England and has been selected for funding by the National Institute for Health Research.

# Why have I been invited?

You have moderately reduced kidney function which is the stage of chronic kidney disease we are investigating. We are asking 1320 patients with moderately reduced kidney function from 6 centres in England to take part.

# Do I have to take part?

No, taking part in the research is entirely voluntary. It is up to you and your decision will not affect the standard of care you receive. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive. If you do not take part or if you withdraw from the study, you will continue to receive your consultant or general practitioner’s usual treatment for chronic kidney disease.

# What will happen to me if I take part?

After receiving this information sheet a research nurse will contact you directly to see if you are willing to participate in the study. **You may also call or be asked to contact your local research team if you are willing to take part**. Following this, you will be offered an appointment to attend the *<insert department name>* at *<insert hospital name>.*

At this appointment, if you are willing to take part, you will be asked to sign a separate consent form. The research nurse will go through an information form with you to check your details and ask about your medications and other illnesses you have or may have had. You will be asked to give your ethnic origin and your height, weight, waist and hip circumference and blood pressure will be measured. You do NOT need to fast on the morning of the test but please avoid eating a meal with high meat or fish content after 10 pm the evening before the appointment. We will take some blood samples (a total of 12 mL, about 3 teaspoons) and a urine sample from you for measurement of kidney function and store some blood and urine for measurement of other kidney markers in a central laboratory. The research team will then give you a small injection of a substance called iohexol into a vein. Four further blood samples will then be taken (4 mL, just under a teaspoon, each time) over a period of four hours to measure how efficiently your kidneys have cleared the iohexol injection from your blood. Where possible, a small needle will be left in place for these four hours to save you the discomfort of repeated injections. In total the procedure takes approximately five hours to complete. This will be the end of your first visit.

You will then be followed up in clinics at 6, 12, 18, 24 and 30 months to assess your kidney function. These visits may be a part of your routine hospital care. On each of these occasions we will ask you to provide a blood sample and a urine sample for tests of kidney function. The final visit will take place after 36 months. At this last visit we will repeat all of the tests and measures we did at the first visit, including the iohexol injection procedure. This will be the end of the study and after this your care will continue as normal.

You may be asked if you would also like to participate in a sub-study (an extra study within the main study) looking at patterns of what happens to chronic kidney disease with time. We will ask 375 of the 1320 patients in the study to be included in this sub-study. Your participation in the sub-study is optional and will be exactly the same as that detailed above but will also involve having the iohexol injection procedure at 12 months and 24 months in addition to the initial and 36 months iohexol injection procedures. At 12 and 24 months your medical history will be taken and height, weight, waist and hip circumference and blood pressure will also be measured again. If you are willing to participate please let the research nurse know at your appointment and you will be asked to indicate your wish to participate on the consent form.

The full schedule of tests and visits we will be asking you to undertake is described below:

Table 1: Schedule of Test and Visits

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Study visits** | Visit 1  Month 1 | Visit 2  Month 6 | Visit 3  Month 12 | Visit 3  Month 18 | Visit 5  Month 24 | Visit 6  Month 30 | Visit 7  Month 36 |
| Informed consent and registration | Yes |  |  |  |  |  |  |
| Medical history, weight/height, waist and hip circumference, and blood pressure | Yes |  | Yes (if involved in sub study) |  | Yes (if involved in sub study) |  | Yes |
| Blood tests (serum creatinine and cystatin C, plus some stored samples for future research) | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Urine test (Albumin; plus some stored samples for future research) | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Iohexol (GFR) clearance test | Yes |  | Yes (if involved in sub study) |  | Yes (if involved in sub study) |  | Yes |

# What is the procedure that is being used?

Iohexol is an iodine containing chemical that is widely used in medical procedures including the measurement of kidney function. In this study, iohexol measured GFR will be the gold standard way of assessing kidney function against which other markers will be compared.

# What are the alternative assessments available?

GFR is also commonly estimated using a blood marker called serum creatinine. In this study we will compare GFR estimated using creatinine with GFR measured using the iohexol test. We will also look at how well GFR can be estimated using a newer blood marker called cystatin C. Note that the iohexol test will not be part of your routine clinical care, which will continue as normal separate to the study.

# What are the side effects of the procedure?

Iohexol GFR measurement is a widely used procedure but very rarely people can have an allergic reaction to the iohexol. The dose of iohexol we are using is much lower than usually used in clinical practice. Sensitivity or allergy to iodine-based products means that you cannot be considered for participation in this research project. You will be specifically asked by the research team about this.

# What are the possible disadvantages and risks of taking part?

The risk of a serious illness as a result of participation in this study is very low. Iohexol has been associated with kidney damage when used at high doses but at the low dose used in this study no kidney damage has ever been reported. There are no other risks other than a potential allergic reaction to the iohexol. The major disadvantage of participation in the study is that the iohexol test at the beginning and end of the study takes approximately five hours to complete.

# What are the possible benefits of taking part?

The results from the blood and urine samples taken as part of the study will not be made available to you or your doctors whilst the study is ongoing; therefore you will not receive any immediate individual benefit from taking part.

The information we get from the study should help us to improve the identification of kidney disease progression and the treatment of people with kidney disease in the future.

# Will I be paid for taking part in the study?

No, there will be no payments for participating. However, we will reimburse any travel expenses or parking charges you have incurred as a result of extra hospital visits or longer visits for the purposes of the study.

# What if new information becomes available?

Sometimes during the course of a research study, new information becomes available about the test(s) that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research doctor will ensure that your routine clinical care will continue. If you decide you wish to continue in the study you will be asked to sign an updated consent form.

# What happens when the research study stops?

When the research study stops the results of the study will be published and the information we get from the study may help us to improve the accuracy for monitoring disease progression in patients with moderate (stage 3) chronic kidney disease. You will be given a copy of the study report if you wish.

# What if there is a problem?

Any complaint about the way you have been dealt with during this study or any possible harm you might suffer will be addressed. The detailed information is given in Part 2.

# Tracking your future health

We would also like to be able to receive information about the future health of people who have taken part in our study. To do this we need to have your permission to send your name, date of birth, gender, and NHS number to the Health and Social Care Information Centre (HSCIC) or the Office for National Statistics (ONS). The information they hold will be used to keep us updated with your health status. This won’t need you to do anything after your last study assessment visit. You can opt out of this part of the study if you want to simply by not putting your initials in the box next to this question on the consent form.

# Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The detailed information is given in Part 2.

# Thank you for reading so far – if you are still interested, please go to Part 2

Part 2 – the details

# What if relevant new information becomes available?

Sometimes, during the course of a research project, new information becomes available about the test(s) being studied. If this happens, your study doctor will discuss how this affects your care and participation in the eGFR-C study. You or your study doctor might consider that you should continue in the study or withdraw. Either way, he/she will explain the reasons and arrange for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form. If the study is stopped for any other reason, your doctor would, again, tell you and arrange your continuing care.

# What will happen if I do not want to carry on with the study?

You can decide not to continue with the study at any time but, if you do, we would still like to be able to keep your data on file and include them in the final study analysis unless you request that they should not be.

# What if there is a problem?

If you are harmed due to someone’s negligence, then you may have grounds for a legal action but 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 should be available to you. Taking part in this study would not affect your legal rights.

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The contact details for the eGFR-C Chief Investigator are: Dr Edmund Lamb, Telephone 01227 766877 extension 74736. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

# Will my taking part in the study be kept confidential?

If you decide to take part in the eGFR-C study all information which is collected about you during the course of the research will be kept strictly confidential in the same way as your medical records. Information about your disease and progress will be sent by your doctors to the eGFR-C study office at the University of Birmingham Clinical Trials Unit, on paper and electronically, where it will be securely stored under the provisions of the 1998 Data Protection Act. If you agree to take part in this study, your GP and the other doctors involved in your clinical care will be notified of your participation in the eGFR-C study. With your permission, your relevant medical records may be inspected by authorised individuals from the Birmingham Clinical Trials Unit or your hospital. They may also be looked at by the study team and regulatory authorities. The purpose of this is to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and will do their best to meet this duty. If you consent to taking part in this study a copy of the consent form will be sent to the Birmingham Clinical Trials Unit.

If you consent to it, the research staff involved in eGFR-C may, in the future, access electronic data from your central NHS records, for example through the Health and Social Care Information Centre (HSCIC). This will provide researchers with information that is routinely gathered and stored during your visits to primary care and hospital, and will allow researchers to find out about your health after the study has ended. By using routinely collected data we will be able to do this without needing to contact you further. In order to do this, we would need to send your name, gender, date of birth and NHS number with any request for information.

In line with clinical trial guidelines, at the end of the study, the data will need to be securely archived (stored) for at least 5 years. Arrangements for confidential destruction will then be made. Should you withdraw consent for your data to be used, it will not be used.

# What will happen to the blood and urine samples I give?

The blood and urine samples will be stored initially in the laboratory at the hospital in which you have been seen. The samples will then be forwarded in batches to central laboratories at Kent and Canterbury Hospital, Canterbury, Kent and St. Thomas’ Hospital, London for the specialised tests. Some blood and urine will be stored at the central laboratories and may be analysed for new kidney markers that become available during the period of the study provided that you have given your consent for this purpose. No DNA (genetic) studies will be done on your samples. The project is scheduled to end after five years and the main results will then be published in a scientific journal. Your samples will be destroyed within five years of the publication of the main research findings.

# What will happen to the results of the research study?

Once the study has finished the results from all patients who took part in the study will be published in a scientific journal. The publication will appear when all the participants have completed the study and the results have been analysed. Your doctor/research nurse can provide you with a copy of this publication if you are interested. We will also publicise the results on the study’s website. Only anonymous data will be published and your name will not appear in any report, presentation or publication.

# Who is organising and funding the research?

The eGFR-C study is being co-ordinated by the Birmingham Clinical Trials Unit at the University of Birmingham and is sponsored by the University of Birmingham and East Kent Hospitals University NHS Foundation Trust. The study Chief Investigator is Dr Edmund Lamb at East Kent Hospitals University NHS Foundation Trust. The study is being funded by National Institute for Health Research Health Technology Assessment Programme. The research has been reviewed and approved by all these organisations.

# Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by South East Coast - Surrey Research Ethics Committee. Research Ethics Committees include healthcare professionals as well as non-medical people, and are completely independent from anyone organising the study. Further details about the National Research Ethics Service can be found at: <http://www.nres.nhs.uk/about-the-national-research-ethics-service/>.

# Where can I get further information?

For queries about the study or for further information please contact:

<Insert Local PI Name>, Telephone <Insert Local PI Tel. No.>, eGFR-C Principal Local Investigator

Dr Edmund Lamb, eGFR-C Chief Investigator, Telephone 01227 766877 extension 74736 or e-mail elamb@nhs.net.

The eGFR-C study co-ordinating centre is located at the:

Birmingham Clinical Trials Unit, Public Health Building,

University of Birmingham, Birmingham B15 2TT

Tel 0121 415 9134, Fax: 0121 415 9135

Web address: [www.birmingham.ac.uk/egfrc](http://www.birmingham.ac.uk/egfrc). Email: [eGFR-C@trials.bham.ac.uk](mailto:eGFR-C@trials.bham.ac.uk).

**Thank you for considering participation in this study.**

**You will be given a copy of this information sheet and your signed consent form to keep if you decide that you wish to take part in the study.**