For Trial Participants

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What is the eGFR-C study?

eGFR-C is a research study in six hospitals across England which will recruit 1320 patients to test methods of estimating kidney function.

Who can participate?

You can participate in eGFR-C if you are 18 or over and suffer from Stage 3 Chronic Kidney Disease (CKD). There are centres taking part in the study in Birmingham, Derby, Kent, Leicester, London and Salford - they are shown on the participating centres page **here (/research/activity/mds/trials/bctu/trials/renal/egfr-c/participants/centres.aspx)** .

What does the study involve?

The study is designed to test different ways of estimating kidney function. The best way of measuring kidney function is time consuming and expensive, so estimates are normally used instead. eGFR-C will look at which method of estimating is most accurate.

If you are willing to take part, you will be asked to sign a 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. We will take some blood samples (a total of 20 mL, about 4 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 then 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. 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 all of the tests and measures from the first visit, including the iohexol injection procedure, will be repeated. This will be the end of the study and after this your care will continue as normal.

In Birmingham, Leicester and King's College Hospital London 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 and 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.

After all 1320 patients have reached the three year test the results will be compared, analysed, and published.

Background to the study

Chronic Kidney Disease (CKD) affects around 1 in 10 people in the UK, and 50 million blood tests a year are used by the NHS to give an estimated measurement of kidney function. Measuring kidney function is important as it helps to diagnose kidney disease and see if it is getting worse.

Usually, a substance in the blood called creatinine is measured to estimate kidney function. However, other substances can also be measured. One is cystatin C, and we want to find out if measuring this instead - or as well - gives a more accurate measurement of kidney function.

More accurate measurement of kidney function will allow doctors to diagnose and treat CKD better.

What are the possible risks and benefits to participating?

There are no risks other than a potential allergic reaction to the iohexol used in the gold standard test. 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.

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.

The results from the blood and urine samples taken as part of the study will not be made available to you or your doctors so you will not receive any individual benefit from taking part in the study.

However, 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.

Study set-up details

eGFR-C will start recruiting in 2014, and the recruitment period will last for 18 months. 1300 patients will be recruited into the main study, including 375 into a sub-study looking at disease progression and ethnic minorities. Another 20 will be recruited into a side-study based in Canterbury. Each patient will be followed up every six months for three years. Once the last patient has had their three year follow up visit, there will be a 6 month period of data analysis and report writing before the study results are published.

The eGFR-C Chief Investigator is Dr Edmund Lamb, based at Kent and Canterbury Hospital.

The eGFR-C study is being co-ordinated by Birmingham Clinical Trials Unit, and is co-sponsored by the University of Birmingham and East Kent Hospitals University NHS Foundation Trust.

The study has been funded by the National Institute for Health Research Health Technology Assessment programme (NIHR HTA Ref: 11/103/01).

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee (REC) to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved on 9th October 2013 by South East Coast - Surrey REC (Reference No: 13/LO/1349). RECs include healthcare professionals as well as non-medical people, and are completely independent from anyone organising the study.

ISTRCTN42955626

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