



**Pregnancy  
Adaptations  
In  
Renal disease  
Study**

**Participant Information Sheet**

You are being invited to take part in a research study. Before you decide to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Please ask if anything is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

**Why have I been invited to take part?**

You have been invited to take part because you are pregnant.

**What are we trying to find out?**

We are trying to find out more information about how kidney disease affects pregnancy. We would like to test your blood and urine so that we can compare your results with women who have kidney disease. This will help us determine which changes are related to being pregnant and which may be due to kidney problems.

Kidney disease affects 3% of women of childbearing age. Most women with kidney disease have successful pregnancies and healthy babies. However, women with kidney disease have an increased chance of developing a condition called pre-eclampsia.

Pre-eclampsia is a condition that only occurs in pregnancy. It can make either the mother or her developing baby unwell. Pre-eclampsia is diagnosed when the mother's blood pressure increases and protein appears in her urine. In women with kidney disease this diagnosis is very difficult as high blood pressure and protein in the urine may be due to her kidney disease and not pre-eclampsia. The only cure for pre-eclampsia is to deliver the baby. It can be difficult to know when we should deliver the babies of women with kidney disease if we cannot be sure whether they have pre-eclampsia or not. We would like a better test for pre-eclampsia that does not rely only on blood pressure and protein in the urine.

Pregnancy also affects how the kidney works and routine tests of kidney function are changed by pregnancy. This means it is difficult to know

whether kidney function is getting worse in pregnancy (kidney injury). We would also like a better test for kidney injury in pregnancy.

We can measure changes in blood and urine in both pre-eclampsia and kidney injury. However, we do not know yet enough about these changes in normal pregnancy to be able to use them. Your blood and urine tests will help us find out more.

### **Do I have to take part?**

No. It is entirely up to you whether you take part or not. The medical care you receive now and in the future will not be affected by your decision. You are free to withdraw at any time without giving a reason.

### **What will happen to me if I do take part?**

You will see one of the doctors or midwives who will answer any questions that you may have. If you agree to take part, we will ask you to sign a consent form and you will be given a copy to keep. We will then take extra blood and urine tests from you during and after your pregnancy. We will also look at yours and your baby's medical records.

### **What will the blood and urine tests involve?**

We will take a minimum of one extra blood test from you, and a maximum of ten during or just after your pregnancy. No blood tests will be taken from your baby. We will do these tests when you attend your normal antenatal appointments so you will not have any extra visits to the hospital. We will try to take blood and urine samples when you are having routine blood and urine tests done. We will take 35ml (6 teaspoons) of blood at each test. We may also ask you to have your

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finger pricked for a small blood sample to be taken and we may repeat this close to the time of birth, to check kidney function and/or markers that might affect kidney function including placental growth factor.

We would also like to test your kidney function on a blood sample which was taken at your first antenatal visit and is stored in case further tests are needed during your pregnancy. The sample will only be used if it has not been required during your pregnancy.

If study blood tests are undertaken at a separate time from routine medical appointments then we will offer assistance with your travel expenses.

### **What will happen to the blood and urine samples that you take?**

These tests will be done in laboratories at King's College London and at other hospitals and universities in the UK. In addition, we may ask companies who develop tests for kidney disease and pre-eclampsia to help us look at your samples. Your samples will be labelled with a study code and will not have your name on them so the laboratories and companies involved in the study will not know who you are. If we need to transport your samples we will do this carefully and with respect.

The results of these research tests will not be available during your pregnancy but we hope that they will give us information for the future.

### **What are the benefits of taking part?**

You will help to provide information that may improve the treatment of pregnant women with kidney disease in the future.

### **What are the possible risks or side effects of taking part?**

There are no risks to taking part. The amount of extra blood that we take will not affect you or your baby.

### **What if new information becomes available?**

You will benefit from any new medical information that becomes available whether or not you take part in the study.

### **What will happen if I don't want to carry on with the study?**

If you do not wish to continue taking part, you are free to withdraw at any time without giving a reason. We will ask if the information and samples already collected can still be used or if you want them destroyed.

### **What if there is a problem?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed.

If you have a complaint, you should talk to your research doctor who will do their best to answer your questions. If you remain unhappy, you can make a formal complaint through the NHS complaints procedure. Details can be obtained through King's College Hospital Patient

Advisory Liaison Service (PALS) on 02032993601 or [kch-tr.PALS@nhs.net](mailto:kch-tr.PALS@nhs.net).

This study is co-sponsored by King's College London and Guy's and St Thomas' NHS Foundation Trust. The sponsors will at all times maintain adequate insurance in relation to the study independently: King's College London (through its own professional indemnity for Clinical Trials and no fault compensation), and the Trust (which has a duty of care to patients via NHS indemnity cover), in respect of any claims arising as a result of clinical negligence by its employees, brought by or on behalf of a study patient.

### **Will my taking part in this study be kept confidential?**

Yes, all information that is collected about you during the course of the research will be kept strictly confidential. If you agree to join the study, your and your baby's medical records and information collected during the study will only be looked at by authorised persons from King's College London and Guy's and St Thomas' NHS Foundation Trust.

### **What will happen after the study has been completed?**

We will ask if you are happy for your blood and urine samples (which will not contain any DNA) and data to be stored anonymously by King's College London in a Research Sample Archive. We could then use your samples in future ethically approved research. Only appropriately trained researchers would have access to your samples. Future

research may involve other academic or commercial partners and your samples may be transferred to countries outside the UK.

We will ask if you are happy for your data from the study to be archived by the National Institute for Health Research Rare Diseases Translational Research Collaboration so that future researchers will be able to understand more about renal disease and pregnancy. Your identity will be protected at all times.

We will ask your permission for these things separately on your consent form, so that you can say no to any part of the study that you are not happy with.

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

The information we get will help us work out if there is a better way of diagnosing pre-eclampsia and kidney injury in pregnant women with kidney disease. The results may be published at conferences and in professional journals but you will not be identified. If you wish to know the results of the study we will send you a summary by e-mail as detailed on your consent form.

### **Who is organising and funding this research?**

The Women's Health Academic Centre (King's College London) based at St Thomas' Hospital is organising this project. This project will be submitted as part of a PhD qualification for Dr. Kate Wiles. The project is funded by the National Institute for Health Research Rare Diseases

Translational Research Collaboration and Kidney Research Stoneygate Foundation Allied Health Professionals Fellowship.

### **Who has reviewed the study?**

The National Institute for Health Research and Kidney Research UK have reviewed the study. In addition, all research in the NHS is looked at by a Research Ethics Committee, which is an independent group of people who act to protect your interests. Wales REC 6 has given ethical approval to this study.

### **What do I do if I have further question or want to take part?**

The research team can be contacted on 0203 299 6725. In an emergency or if you are very worried and wish to speak to a midwife or doctor about your health, we recommend that you contact your local maternity services as listed on your hand-held maternity records.