

Participant Information Sheet

Raman spectroscopy and gestational diabetes

REC: 19/SW/0196LO/0722

A research team at Swansea University Medical School and Swansea Bay University Health Board (SBU HB) is carrying out a research study. The purpose of this research study is to see if we can develop a better test for diagnosing gestational diabetes, a type of diabetes that occurs in pregnant women.

Who is being invited to participate and why?

If you are having a glucose tolerance test as part of your normal care in pregnancy to determine if you do or do not have gestational diabetes, Swansea University Medical School would like to invite you to take part in our research study by providing an extra sample of blood while the sample for this test is being taken. This blood sample will be used to develop a better way of testing for gestational diabetes and helping us understand why diabetes occurs in some women when they are pregnant. We will use the blood sample to measure molecules that circulate in your blood and might indicate that you have gestational diabetes and study how these molecules as well as the different immune cell types might contribute to the development of gestational diabetes.

Joining the study is entirely up to you. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide if you would like to take part and answer any questions you may have. This should take about 10 minutes. Please feel free to talk to others about the study if you wish. The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part. Then we give you more detailed information about the conduct of the study. Do ask if anything is unclear. If you would like more information or have any more questions, you can also contact the research team whose details are provided at the end of this information sheet.

What is the purpose of the study?

Pregnant women sometimes undergo a glucose tolerance test at around 20 – 30 weeks of pregnancy to see if they have gestational diabetes. This test requires overnight fasting then attending hospital for a few hours the following morning. At hospital your blood is taken, you are given a glucose containing drink, and then another blood sample is taken after about two hours. Glucose levels in your blood before and after the glucose containing drink determine whether you have diabetes. We are developing what we hope will be a much simpler and quicker test. The purpose of this research study is to compare our test to the glucose tolerance test and to better understand why our test might be able to diagnose gestational diabetes.

We think this study will help us to understand these important changes that ensure pregnancy is successful and this study might also provide insight into poor pregnancy outcomes such as miscarriage and premature delivery.

What will taking part involve?

We would collect up to 20mls of blood which is equivalent to four teaspoonfuls. This blood sample would be taken at the same time as the blood sample being taken at the start of your glucose tolerance test. This would be the only blood sample that we take from you. The blood sample will be transferred to Swansea University for analysis and storage. We will use this sample to measure molecules and cells that circulate in your blood. Some of these measurements might be made by researchers in other parts of the UK or the world. We will also ask you some questions about your health and access your medical notes for information about your baby (e.g. birth weight, sex) after it is born. We will store unused samples for further investigations arising from our findings. These samples will be stored for up to 15 years and we will seek your consent for this specifically.

Will genetic testing be done on my samples?

The cells in your blood sample contain genes which are made up of DNA (deoxyribonucleic acid). DNA provides building blocks for the cells in your body and RNA (ribonucleic acid) is involved in the building process. We will look at differences in how the activity of genes related to the development of gestational diabetes are controlled which might include analysis of the DNA and RNA in your cells. These results are for research only.

What are the possible benefits from taking part?

There are no immediate benefits for you or your baby from taking part in this study.

What are the possible disadvantages and risks of taking part?

Taking the blood sample from you may cause bruising and some minor discomfort.

What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether to take part. You do not need to take part in this study and not taking part will not affect your standard of care. 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 do decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself. Please contact Professor Cathy Thornton on c.a.thornton@swansea.ac.uk if you would like to withdraw. As your data and stored samples will have been anonymised it will not be possible to remove them from the research project, but we will not collect any further data about you or your baby. This does not affect your data protection rights. If you want to take part in this study but do not want your samples used for other research studies, you can still take part. You can indicate on the consent form that you do not want your samples used for other research projects.

What will happen to the results of the study?

The research team will record all data in special forms and combine it with the information from everyone else in the study. We will summarise our findings in a study report which we will send to all study participants. The findings also might be published in a scientific journal or presented at a scientific meeting. Your identity will remain anonymous in all publications and presentations of the findings.

Who is organising and funding the research?

The study is organised and carried out by a research team at Swansea University. The study is funded by Diabetes UK who are a UK charity that support research on all types of diabetes. Some of the laboratory work will be done by PhD students who are conducting the research as part of obtaining a PhD.

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 interests. This study has been reviewed and given favourable opinion by London - Westminster Research Ethics Committee.

How will we use the information about you?

We will need to use data from you and from your medical records. This information will include your name, NHS number, postcode, and age. People will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure. We will not share your information with anyone outside of the research team – if we share any of your blood sample with other researchers it will not involve sharing personal data about you. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/ or our leaflet available from Swansea University by sending an email to directly to the Swansea University Data Protection Officer (dataprotection@swansea.ac.uk)

Will my data or samples be used for future research?

When you agree to take part in a research study, the information about your and your baby's health and care as well as the samples you provide may be used in future research studies including being provided to researchers running other research studies in Swansea University and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the [UK Policy Framework for Health and Social Care Research](#).

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. We will seek your consent for this specifically.

What if something goes wrong?

If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, then you should contact:

SBU HB Community Health Council
First Floor, Cimla Hospital
Neath SA11 3SU

Phone 01639 683490

Website: <http://www.wales.nhs.uk/sitesplus/902/home>

If you wish to complain about the management of your data, the data controller for this project will be Swansea University. The University Data Protection Officer provides oversight of university activities involving the processing of personal data and can be contacted at the Vice Chancellors Office: dataprotection@swansea.ac.uk. Your personal data will be processed for the purposes outlined in this information sheet. If you have any complaints about the research project staff then you should contact the Head of Swansea University Medical School (email: c.a.thornton@swansea.ac.uk).

Where can I get more information?

You can get independent advice about taking part in research from the following website:

People in Research - <http://www.peopleinresearch.org/>

If you require further information about the study, you can contact a member of the research team:

Name	Position	Telephone	Email
Professor Cathy Thornton	Chief Investigator	01792 602122	c.a.thornton@swansea.ac.uk
Oliver Richards	Research Assistant	01792 602237	o.c.richards@swansea.ac.uk
Dr April Rees	Co-investigator		April.Rees@swansea.ac.uk

Thank you for taking the time to read this information sheet.