**Study Title:** Multi-Parameter Analysis of Platelet Function: The Impact of Cardiometabolic Disease - The **RE**adin**G** plat**E**let fun**C**tion stud**Y** - REGENCY

We would like to invite you to take part in our research study. This is a study led by researchers at both the Royal Berkshire Hospital and University of Reading, funded by the British Heart Foundation (BHF). To help you decide whether to participate 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 by telephone and answer any questions that you have. We would expect that this should take about 20 minutes. Please talk to relatives, friends or your clinical care team about the study if you wish, and ask us if anything is not clear.

**What is the purpose of the study?**

Small blood cells called platelets help blood to clot when we injure ourselves, but occasionally they form dangerous clots inside blood vessels that can cause heart attacks. People may be prescribed anti-platelet drugs that help to stop platelets from forming dangerous clots, but they do not work for everybody.

Researchers at the University of Reading have found that the way people’s platelets work varies. These differences might make certain anti-platelet drugs more or less effective for some people. This might be particularly important for people with type 2 diabetes mellitus, who are at increased risk of kidney failure, heart attacks and other forms of cardiovascular disease.

The study is looking into platelet function in four groups of patients: individuals with and without heart disease, and patients with and without type 2 diabetes mellitus. Blood samples will be used to identify differences in the way platelets work in diabetic and non-diabetic patients and test the effectiveness of antiplatelet drugs in a laboratory. This information will help researchers and clinicians understand why heart disease is more common in diabetic patients. This will assist in the development of new treatments and guide the use of existing antiplatelet drugs to maximise their safety and effectiveness for individual patients.

**Why have I been invited?**

You have been invited because you are scheduled to undergo an angiogram. The study includes diabetic and non-diabetic patients with or without coronary artery disease (narrowing of blood vessels to the heart) and will include participants of all cultures, backgrounds and ethnicities. It is very important that participants understand fully what will happen in the study and why they specifically have been approached, in order that they can provide their consent to take part.  Where a potential participant is not able to fully understand the study information they will not be included in the study (it will not be feasible to provide translation services).

**Do I have to take part in the study?**

It is up to you to decide to join our study. If you do agree to take part in the study we will ask you to sign a consent form. You are free to decline or withdraw your consent at any time, without giving your reason for this. Your decision whether or not to participate in the study would not affect or change any standard care that you receive.

**What do I need to do if I take part?**

Our aim is to make our study as easy as possible for you. If you agree to take part, you will be asked to complete a consent form and donate some blood samples.

**Blood tests:** During your angiogram appointment, up to 50ml (Equivalent to 10tsp) of blood will be taken. You may have had similar volumes of blood taken for routine tests by your doctor. This amount of blood is expected to be

replaced by your body in just a few hours. We may also collect body composition measurements such as height, weight, hip and waist circumference and body fat percentage. With your permission, we will then link these measurements and results from tests using your blood with information taken from your NHS hospital records including the result of your angiogram.

As an **optional** part of the study, a small group of people will be requested to return for further blood sample analysis to ensure reproducibility. We will also conduct molecular studies of platelets and proteins, in order to determine why there are differences in platelet function between the different groups. This is likely to be within 2 years of your angiogram appointment but may be up to 5 years after the start of the study. You will be reimbursed for travel expenses in this instance and you can choose to have the blood sample taken at either the Royal Berkshire Hospital or the University of Reading.

With your consent, your GP will be notified of your participation.

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

While we cannot promise that the study will help you directly, the information we get from this study will be used to improve the treatment of patients with ischaemic heart disease and type 2 diabetes mellitus nationally and internationally. There will be no payment for participation in the study other than reimbursement for travel costs incurred for repeat blood sampling.

**What are the disadvantages of taking part in the study?**

The blood sampling procedure may cause mild discomfort or pain or may cause minor bruising where the sample is taken from.

If we find anything incidentally during the tests that might be significant to your health, with your consent, this information would be passed onto your healthcare team.

Your angiogram is part of your routine care. If you take part in this study you will not undergo any additional angiograms. These procedures use radiation to form images of your body and provide your doctor with other clinical information, in a similar way to having an X-ray.  The risks to your long term health that is associated with this radiation are low, and will be unaltered whether or not you take part in this study.

**What happens at the end of the study?**

A lay summary of the results will be made availableto all participants on request, and we would be pleased to explain the outcomes to you personally.

The consent form asks you for permission to preserve the data derived from your samples over the long term, and to make the data available, in anonymised form, either openly or subject to appropriate safeguards, so that they can be consulted and re-used by others, in accordance with the University’s Research Data Management Policy.

**How will we use information about you?**
We will need to access information from your medical records for this research project. This information will include your initials, NHS number, name and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. All will have a duty of confidentiality to you as a research participant and we shall follow Good Clinical Practice guidelines (an internationally recognised standard for conducting clinical research) for which all team members are trained.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

All procedures for handling, processing, storage and destruction of data are in accordance with established arrangements known as Caldicott principles and the Data Protection Act. We will keep all information about you safe and secure. 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 by asking one of the research team using the details on the final page.

Long term storage of your blood samples will not be necessary, although while the tests are carried out they will be held securely at the Royal Berkshire NHS Foundation Trust or the University of Reading. These samples will not identify you at any stage during the process.

**What will happen to any samples I give?**

Your samples will be allocated a unique number that cannot identify you and will be stored in this anonymised form. They will then be transferred to specialist laboratories at the University of Reading for platelet function tests and molecular analysis.

If any results of individual significance to you are found, they will be fed back to your clinical care team. You will retain the right to choose whether to access this information. You would not personally benefit financially if there is commercial significance from the outcomes of the study.

Long term storage of your blood samples will not be necessary. After your samples have been analysed, they will be destroyed using appropriate clinical waste bins.

**What will happen if I don’t want to carry on with this study?**

You can stop being part of the study at any time, without giving a reason, but we will keep information and data from your samples that we already have. Please contact a member of the research team if you decide to withdraw from the study.

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

If you have a concern about any aspect of the study, you should ask to speak to the researchers who will do their best to answer your questions (see details at the end of this information sheet). If you still remain unhappy and wish to complain formally, you can do this by contacting the Patient Advice Liaison Service (PALS) within the Royal Berkshire Hospital. Contact details are as follows:

Email: talktous@royalberkshire.nhs.uk

Telephone: 0118 322 8338

The University of Reading, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm arising from the negligence of the University, or that of a collaborator in this research, and harm resulting as a direct consequence of your participation in this trial. NHS indemnity operates in respect of the clinical treatment provided.

If you wish to discuss any aspect of the way in which you have been approached or harm resulting from the course of this study, you should contact Professor Jonathan Gibbins (j.m.gibbins@reading.ac.uk, 01183787082) or a member of the Cardiology Research Team on 0118 322 7260 or email rbft.cardioresearchteam@nhs.net . You can also contact the PALS team using their details above.

**Who is organising and funding the study?**

The study is organised by Prof Jonathan Gibbins (University of Reading), Dr Neil Ruparelia, Dr Charles McKenna and Ms Abigail Whyte and Mr Mark Brunton (Royal Berkshire Hospital). The study is being funded by the British Heart foundation

**Who has reviewed and authorised this study?**

This research study was reviewed and given favourable opinion for conduct by the Greater Manchester South Research Ethics Committee and the University of Reading Research Ethics Committee. The study was also reviewed as part of the Royal Berkshire NHS Foundation Trusts R&D governance process.

**Will my taking part be kept confidential?**

Yes, all data will be anonymised prior to being published in reports or publications. If we find anything of significance that needs to be passed to your healthcare team, we will ask for your consent before informing them.

**Contacts for this study:**

**Professor Jonathan Gibbins**

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<https://regencytrial.wordpress.com/>

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rbft.cardioresearchteam@nhs.net

**Research and Development Governance Core – 0118 322 8140**

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