ADIPOREDOX STUDY- NEWS

Division of Cardiovascular Medicine, University of Oxford | **15th September 2017**

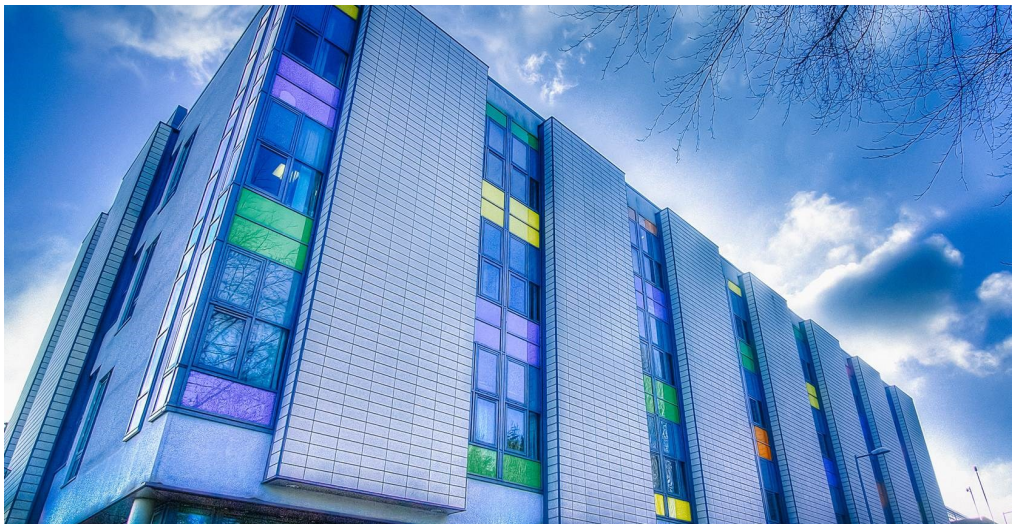
Interactions between adipose tissue, vascular wall and myocardium in human atherosclerosis

Thank you!

From the research team based at the John Radcliffe Hospital (JRH), we would like to thank you again for your participation in the AdipoRedOx research study during your stay for heart surgery. This study is run by a group of study investigators based in the Division of Cardiovascular Medicine, University of Oxford. In this newsletter we would like to update you with the data processing activities, recent outcomes of the study and any ongoing research activity.

In this newsletter we will include:

- A reminder of what the study is about
- Data processing activities
- Recent press release
- The study team and how you can contact us for further information or withdraw from the study



Oxford Heart Centre, opened in 2009. Photo courtesy of Joshua Chai.

A reminder of the study…

Before your heart surgery at the John Radcliffe Hospital, a study investigator approached you to take part in this research because you were about to undergo coronary artery bypass grafting or valve repair/replacement surgery.

We are investigating the mechanisms by which the fat tissue, the vessel walls and the heart muscle interact and we aim to explore whether aspects of this interaction can predict the outcomes of coronary artery bypass grafting operation (CABG). Many different laboratory techniques will be used to analyse the samples collected from participants which will include current established techniques as well as newly developed techniques that become available during the course of the study. The success of bypass graft surgery will be further assessed in participants undergoing CABG using Computed Tomography Angiogram (CT-A) to determine if the flow through the graft is normal (the vein graft patency).

After you signed the study consent form, you may have undergone an ultrasound scan of your arm (FMD). This was to measure the function of the inner lining (endothelium) of the artery and assess how well it dilates (enlarges) in response to an increase in blood flow. You may have also had a scan of your neck (looking at the carotid arteries), scan on your legs and abdomen for measures of fat underneath the skin and a heart scan. Samples of vessel obtained by the surgeon during surgery were then tested in the laboratory for further measures of endothelial function.

The information from the additional tests would have been combined to investigate any predictive value of clinical outcome based on: risk factors and medication at time of surgery and clinical outcome based on medical records.

Study participant having an ultrasound of their arm .

Laura Herdman, lead of patient recruitment team of AdipoRedOx study.

Radcliffe Department of Medicine

This study is part of the Oxford Heart Vessels Fat (Ox-HVF) cohort, which consists of a cluster of clinical studies (namely ART Vascular, Bypass Grafts, AdipoRedOx, ORFAN and IMPACT), which provide results allowing the deployment of a multi-level strategy to understand the mechanisms of cardiovascular diseases. As each one of the individual studies approaches the issue of cardiovascular disease pathogenesis from a different angle, the OX-HVF cohort provides a unique and powerful platform and the strength of the cohort is the direct access to human tissue (vessels, myocardial and fat biopsies, DNA, plasma and others), in combination with extensive non-invasive cardiovascular phenotyping that includes cardiovascular computed tomography angiography, ultrasound and others. The OX-HVF cohort also collects prospective 10-year clinical outcome data and is linked to the NIHR Bioresource . Combination of pseudonymised research data obtained from any study under the OX-HVF cohort will add value to the research results and potentially allow the translation of the findings into clinical applications.

Study Recruitment

This study is aiming to recruit 700 participants undergoing coronary artery bypass graft surgery (CABG) and 300 undergoing heart valve repair/replacement surgery. Inclusion of participants who do not have coronary artery disease (CAD) is equally important as it will allow us to check if the research findings observed in CABG participants are indeed related to the underlying CAD, rather than the effect of heart surgery alone. The study is actively recruiting until 2020 and will follow participants up until 2030.

Left: FMD ultrasound scan. **Right Study investigator measuring endothelial function in the laboratory**

Data processing activities..

We would like to further explain how we are using your data to obtain information that relates to the study objectives and outcomes.

To keep your research records up to date throughout the duration of the study we will send your unique Study ID number, NHS number, date of birth, postcode and date of Surgery to NHS Digital (https://digital.nhs.uk/article/219/What-is-NHS-Digital-) so they can link this information to all your hospital admissions information. These records are called Hospital Episode Statistics (HES) and are held with NHS Digital. The information returned to us with data about any health outcomes from NHS Digital will only be linked to you by your individual study I.D. and therefore is in a pseudonymised format that only the 'Data Controller' (in this case the Chief Investigator) can de-identify and link back to your name, hospital number and personal details.

NHS Digital will also link your NHS number and date of birth to civil registration data held by the Office for National Statistics (ONS) which will provide us with information regarding mortality of study participants over the time period of this research; this includes date and cause of death.

Who is this data shared with?

The data collected from NHS Digital and ONS will only be accessible to the Chief Investigator and University of Oxford study Investigators and will be in a pseudonymised format that only the data controller can de-code. All personal information exchanged between the study and NHS Digital is protected and encrypted in line with strict regulations and codes of practice that ensure high security standards.

The data will be retained for the duration of the study and will be archived for up to 3 years after the study ends by the AdipoRedOx Study team in the Division of Cardiovascular Medicine, University of Oxford.

Should you wish to opt out of this data sharing/processing between the University of Oxford and NHS Digital and the ONS, please contact us via the study website at: https://oxhvf.com/about/ or the contact information provided in the information box on this page.

NHS Digital

Office for National Statistics

Contact Us:

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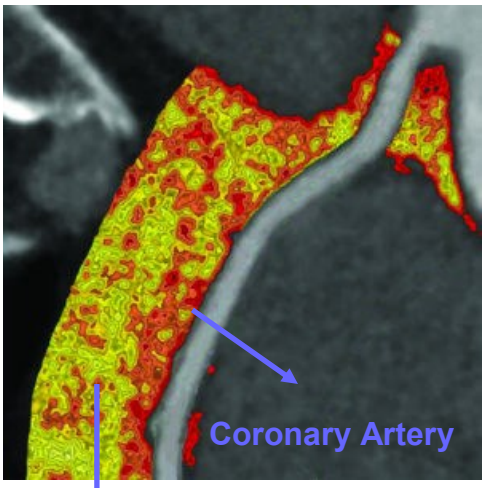
In The News!

Some of our research participants who underwent coronary artery bypass graft surgery were invited back to have a Computed Tomography Angiogram (CTA) to assess their new bypass grafts after surgery.

The CT images and the clinical data collected from the participants' medical records helped us to publish a recent paper that gathered a lot of media attention. Following publication on 12/07/2017 in Science Translational Medicine, press releases followed on 13/07/2017 that included BBC News, The Guardian, The Financial Times and CBN.



Fat surrounding artery- formally known as peri-vascular fat (PVAT).

A new imaging technique has been developed that looks at the composition of the fat surrounding the coronary arteries. This helps to determine which coronary arteries are inflamed which is a process that precedes plaque formation. These plaques can lead to blockages in the coronary arteries.

Having scanned our research participants who had known coronary artery disease (and underwent bypass graft surgery) versus participants without coronary artery disease enabled us to see how the fat around the vessels differ between the two groups.

This is still an exploratory technique that is not (yet) approved for clinical use. We hope that in the future it will help guide clinicians in how they manage and treat patients even in the absence of artery narrowing's. Furthermore, more preventative strategies can be applied to lower the risk of future heart attacks.

Please find the link to the BBC story:

http://www.bbc.co.uk/news/health-40593026

Please find the link to more detailed coverage from Oxford Biomedical Research Centre:

https://oxfordbrc.nihr.ac.uk/oxford-researchers-develop-new-early-warning-scan-for-heart-attacks/

The Study Team

Prof Charalambos Antoniades is the Chief Investigator of AdipoRedOx study**.**

Prof Antoniades is an Associate Professor of Cardiovascular Medicine in the Division of Cardiovascular Medicine, University Of Oxford and an Honorary Consultant Cardiologist in the Oxford University Hospitals NHS Foundation Trust.

He is based at the John Radcliffe Hospital where he heads a research group with a primary focus at looking at oxidative stress in human atherosclerosis.

Laura Herdman, is one of the members of his research group and works as a Clinical Research Technician. Laura or Alex (see pictures on Page 2) may have recruited you to the study and performed the ultrasound scans at your bedside before surgery.

Other study investigators include: Professor Keith M Channon, Professor Barbara Casadei, Professor Robin Choudhury, Mr Rana Sayeed, Mr Mario Petrou, Mr Ravi De Silva, Mr George Krasopoulos, Dr Regent Lee, Dr Alexis Antonopoulos, Dr Marios Margaritis, Miss Laura Herdman, Miss Sheena Thomas, Mr Ioannis Akoumianakis, Dr Evangelos Oikonomou, Dr Jennifer Mancio, Miss Akansha Tarun, Dr Nikant Sabharwal, Dr Andrew Kelion, Dr Cheerag Shirodaria, Dr Raman Uberoi, Dr Susan Anthony and Professor Stefan Neubauer.

.Further Information

If you wish to contact the team for **further information**, or **withdraw** from any part of the study please use the 'Contact Us' tab at the bottom of the AdipoRedOx study web page at: https://oxhvf.com/about/ and a member of the research ream will respond promptly. Alternatively please use the contact details on page 4 of this newsletter.

Acknowledgment of Support:

We are grateful to the following funding bodies for supporting this research:

NHS National Institute for Health Research

SANOFI

European Commission

British Heart Foundation