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The Oxford Risk Factors And Non-invasive Imaging Study (ORFAN) – Arm 4 - Privacy Notice

Summary of the ORFAN Study

ORFAN is a multi-centre cohort observational study involving patients undergoing computed tomography angiography (CTA) or who have had a CTA or CT chest, abdomen and pelvis scan in the past and patients attending outpatient clinics.

The study has two main objectives:

1. To investigate whether biomarkers of metabolic risk can predict major adverse cardiovascular events
2. To identify novel biomarkers able to predict cardiovascular disease pathogenesis and extent of pre-existing vascular disease

The study consists of 4 Arms. This Privacy Notice is for Arm 4 only.

Arms 1, 2 and 3 with a total of 15,500 participants will be prospectively consented to address objectives of the study. The outcome data of these participants are collected through NHS digital with whom a data sharing agreement has been singed already (DARS-NIC-392669-T1F8B).

Arm 4 includes further 250,000 participants (200,000 - in the UK; 50,000 - internationally) who have undergone cardiac CT scans. This study arm focuses on collecting CT images, patient demographics, clinical information including outcomes to aid the development of new image analysis algorithms and software tools (using artificial intelligence and other approaches) to allow automation of the image analysis processes (such as the automated calculation of Fat Attenuation Index) used in Arms 1-3. This study arm will grant us the statistical power to use artificial intelligence based statistical approaches to address both our study objectives. In Arm 4 we are also studying the influence of COVID-19 infection on the cardiovascular outcome measures of the study.

What data is collected and why we need the data

For Arm 4 it is important to understand the flow of data through the study.

Individual patient consent will not be sought for Arm 4 as patient identifiable data will not be recorded by the study team at the University of Oxford.

Identifiable data such as NHS Number, name, date of birth, gender and address are collected by local clinical teams at the local NHS Trust where the participant underwent the CT scan of relevance to the study. The local clinical teams will collect this identifiable information as well

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as health related information for the study relevant to the specific participant. No identifiable information is shared with the research team managing the study at the University of Oxford. Only the local clinical team collects and manages identifiable data. Non-identifiable data will be shared with the research team at the University of Oxford. These data are linked to the participant through a unique trial number which is held only by the local clinical team at the NHS Trust where the participant was treated. Some information that is commonly regarded as sensitive in nature is collected as part of this process. Below we outline what this information includes and why this information is important for our research:

- Race information – racial background is an important variable to include in any models that try to predict individual cardiovascular risk, as unfortunately we know that disease risk is not uniform across races, and we must adjust our models for this so we can ensure the best risk assessments are created for all patients regardless of race.
- Ethnic background information – we collect ethnicity data because, similar to race, ethnic background is an important variable to include in any models that try to predict individual cardiovascular risk, as unfortunately disease risk is not uniform across ethnic groups who have longstanding genetic and epigenetic predisposition to certain diseases and as such we must adjust our models for this.
- Genetic data – no genetic data is collected in ORFAN Arm 4, as we do not collect any human tissue (including blood samples) from participants.
- Health data – we collect health data related to all study participants, and are required to do so in order to conduct high quality healthcare related research. The data that we collect is all utilised to understand the health condition of the participants, such as what medical conditions they have suffered from, and how they were treated for these conditions. These data are imperative to the successful achievement of our research aims.

By way of summary, the health-related data that we intend in to collect in ORFAN Arm 4 includes, but is not limited to, the following health related information:

- Anthropometrics (never those used for biometric identification purposes): Height, weight, waist and hip circumference.
- Clinical data at the time of the relevant CT scan for our study, such as blood pressure, heart rate and heart rhythm.
- Relevant medical history including previous diagnoses of coronary artery disease, presence of heart arrhythmias, previous strokes, previous procedures such as coronary stents, coronary bypass surgery, atrial ablation therapy and aortic valve procedures. We also collect data on reasons for hospital admissions following the relevant CT scan for our study, usually through discharge diagnosis and listed co-morbidities. We do not collect and retain data for hospital attendances that are not related to relevant disease processes of interest to our study.

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- Blood test results at the time point closest to the CT scan of relevance to our study: Lipid levels, circulating inflammatory markers and standard blood tests such as full blood count and electrolytes. We do not collect multiple blood test results.
- Medications: If patients are on cardiovascular medications such as anti-platelets (for example aspirin), anti-coagulants (for example warfarin), statins (for example Lipitor), and/or anti- hypertensives we collect this information. We do not collect detailed medication histories related to dispensing of medications.
- Death data such as date and cause of death if relevant

We do not collect any data related to participants criminal conviction and offenses, religious beliefs, political opinions, trade union membership, biometrics that are used for identification or sex life or sexual orientation information.

The use of NHS Digital data and data held by national registries

The clinical outcome data of Arms 1, 2 and 3 participants are collected through NHS digital with whom a data sharing agreement has been singed already (DARS-NIC-392669-T1F8B).

Similarly, we are planning to collect clinical outcomes data for patients included in Arm 4. This will occur via the sharing of identifiable data such as participant NHS Number, name and date of birth between the local researchers at each study site and the relevant organisations such as NHS Digital, the Office of National Statistics (ONS), or an approved national registry such as the National Institute Of Cardiovascular Outcomes Research (NICOR), The Sentinel Stroke National Audit Programme (SSNAP) or any other NHS affiliated service or registry that collects relevant clinical event data. Practically, the data is then matched utilising the identifiable information provided, and a final copy of the database is created that includes the unique trial number provided by the local NHS Trust and the clinical outcome information, but not any of the identifiable information. This file is then securely sent to the research team at the University of Oxford for analysis. This approach ensures that only the local clinical team at the site where the participant was treated will continue to hold the patient identifiable data. By way of example, the sort of clinical outcomes data we will collect will include data, such as the occurrence of a heart attack or stroke and when this occurred, or the occurrence of an admission to hospital for chest pain and the discharge diagnosis. Without the collection of these outcomes data this research will not be possible, and we would not be able to produce more accurate means to assess patients' risk of heart disease.

This study has been reviewed and approved by the Oxfordshire Research Ethics Committee C [REC reference number: 15/SC/0545]. More details about the study can be found on the following website: www.oxhvf.com/the-orfan-study.

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The University of Oxford, as sponsor of this study, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible.

The legal basis for the processing and storage of personal data for ORFAN is that it is 'a task in the public interest' (article 6(1)(e)) and, that sensitive personal data is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes (article 9 (2) (j), based on Article 89(1)).

The data that we receive and analyse will be identified by a trial number only, and you will not be identified by name, date of birth, NHS number or address by the research team at the University of Oxford. The information received from NHS Digital regarding the ORFAN Study Arm 4 patients will be imported into a database held securely by the University of Oxford and used solely for academic research purposes. Importantly, whilst the information received is specific to each trial participant, no individual person will be identifiable in any publication arising from this work.

Under Section 251 of the NHS Act 2006, we have permission to conduct this study without consent.

We have special permission to conduct the HPS study without study-specific consent (i.e. link, transfer, process and analyse the data) from the Confidential Advisory Group. This permission is given under Section 251 of the National Health Service Act 2006 and its current regulations, the Health Service (Control of Patient Information Regulations 2002) (CAG reference number: 20CAG0157)

What to do next?

If you decide you do not want your data to be linked in this way you can withdraw from this follow-up, without affecting your current medical care, by contacting the study team, who would require your identifiers to then inform NHS Digital that you no longer wish to be part of the cohort. NHS Digital will not provide us with data for anyone who has withdrawn consent.

Data protection regulation provides you with control over your personal data and how it is used. For ORFAN Arms 1, 2 and 3, when you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Participants in Arm 4 do not provide direct consent, however data from any patients who have opted-out of such research via NHS Digital or other national registries, will not be included in this research. Further information about your rights with respect to your personal data is available at https://compliance.admin.ox.ac.uk/individual-rights or by

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contacting the study team using the details below. The University's data protection officer can be reached at data.protection@admin.ox.ac.uk.

If you have further questions or are not happy with the way your data has been handled, please contact the study team using the contact details below. Alternatively, you can contact the study sponsor on 01865 616480 or ctrg@admin.ox.ac.uk. You have the right to lodge a complaint with the Information Commissioner's Office (0303 123 1113) or www.ico.org.uk.

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