Oxford University Hospitals NHS
NHS Foundation Trust

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PARTICIPANT INFORMATION SHEET: Community Participants

Study name: Phase Two of the Valvular Heart Disease (VHD) Population Cohort Study (OxVALVE)

You are being invited to take part in Phase 2 of this research study. Before you decide, 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, relatives and your GP if you wish. Information about the study, including a copy of this information leaflet, can be found on our website: www.oxvalve.nhs.uk.
Ask us if there is anything that is not clear or if you would like more information. Thank you for reading this.

In Brief:

The study is looking at the valves of the heart. Original participants will be invited to re-attend for a long term follow up appointment (approximately 5 years) at their GP surgery which will include a review of their medical history, physical examination, an ultrasound scan of the heart and a blood test. All participants need to be willing to undergo both of these tests to be included in the study. The appointment will last approximately 60-90 minutes.

What is the purpose of the study?

The main purpose of Phase 1 of the OxVALVE study was to find patients with unrecognised heart valve problems in order to study valvular heart disease further and to see how common it is. The secondary purpose in Phase 2 is to study what happens to any abnormality of the heart valves over the long term, and assess if any changes have occurred in those patients whose heart valves were originally normal.

Valvular heart disease (or VHD) is the name given to any malfunction or abnormality of one or more of the heart's four valves. In a normally functioning heart, valves keep blood flowing in the right direction and entering or leaving the heart's chambers only at the right time. VHD can develop before birth (congenital), be caused as a result of the effects of certain infections, or by age-related "wear and tear". However, symptoms vary from person to person and are usually not apparent until the disease is significant and requires medical or surgical treatment.
For these reasons, VHD is poorly researched compared with other heart disease. We want to discover, via a screening programme of adults aged 65 or over, whether early detection and treatment of VHD may improve the care pathways and health of patients in the long term. In order to study this, we need to identify people who have early signs of VHD.
Additionally we will seek your views via a posted questionnaire about how acceptable you have found the screening process. This will help us respond to patients' needs in future screening programmes.

Why have I been chosen?
We aim to re-screen 4000 patients registered with GPs throughout Oxfordshire. You have been chosen because you previously took part in Phase 1 of the study.

Do I have to take part?
The study is designed to cause minimal inconvenience to you. It is up to you to decide whether or not to take part. If you decide to take part, you are free to withdraw consent at any time without giving a reason. This would not affect the standard of care you receive. If you decide that you no longer wish to continue with the study, we would like to retain any data already obtained about you, unless you request otherwise.

What will happen to me if I agree to take part?
You will attend your local GP practice on one occasion for a follow up scan to see whether anything has changed since your original scan.

Will my travel expenses be paid?
We will reimburse you for travel expenses incurred whilst attending study visits. This includes travel by car, taxi or bus as well as associated car parking charges.

Phase 2 visit (approximately 60-90 minutes duration)
We will make an appointment for you in one of the OxVALVE clinics at your local GP practice to take part in phase 2 of the screening programme.
If you are willing to continue to participate in the study:

1 You will be asked some questions about yourself and your general health. Some of these relate to your background, including where you were born and how long you have lived in the UK. These are important as some parts of the world have more valve disease than others. This information will never be used outside of the study.

2 We will carry out a simple examination: check your pulse, weight and blood pressure.

3 We will take a blood sample (approximately 3 tablespoonfuls). This will be used to measure the levels of certain disease markers in your blood and provide a baseline for future testing. Some will be stored for possible future testing (including possible DNA testing).

4 We will perform an ultrasound scan of your heart (an “echocardiogram” or “echo”). This is a safe and painless procedure that takes approximately 20-30 minutes. You will be asked to lie on a couch on your left side. A “probe” is placed on your chest and lubricating jelly is used to make good contact with the skin. Ultrasound waves then create images of your heart on the scanner monitor and we are able to look at the overall structure and function of your heart, including the valves.

5 You will be asked to complete some simple questionnaires.

6 We will also ask you to wear an activity monitor (on a wrist band) to assess your normal patterns of activity, and an ambulatory heart monitor (to assess your heart rate and rhythm). These monitors will record over a 5-7 day period. You can then, drop them at your GP surgery or arrange for home collection with the study staff at the time of your visit.

What are the possible results from measurements taken at this **Visit?**
The Echo scan will be assessed by experts. You will receive a letter (which will also be sent to your GP) with one of the following results:

1 No significant valve problems. Preliminary results from Phase 1 have shown that 8 out of 10 patients were found to have no significant valve problem. This can mean either:

   a A normal scan which requires no action on the part of your doctor. Subject to your consent, your data will be kept on the OxVALVE secure study database. You are free to decline this invitation or ask for your contact details to be removed from the database at any time.

   b An abnormal scan suggesting other problems unrelated to valve disease. Although we will not be looking for undiagnosed health conditions other than VHD in this study, we feel a duty as doctors to report any chance findings which arise from the research results. With your permission we will refer these findings to an appropriate health care professional (usually your GP).

2. Progression of your previously known valve disease (diagnosed in Phase 1 of the study). We will notify you of the results of your scan and our highly trained staff will discuss the implications with you and your GP

3. New valve problem, not previously present on the scan from phase 1 of the study. This is likely to be a very small number of people. We will notify you of the results of your scan and our highly trained staff will discuss the implications with you and your GP.

Screening questionnaires.
Participants may be sent additional short questionnaires to complete before and after this visit. These questionnaires will ask you about your state of health and your quality of life, as well as finding out whether the scan made you anxious or was uncomfortable for you.

Cognitive Assessment
This straightforward test will be administered by the OxVALVE team who will ask you a few simple questions and to perform simple tasks to assess your memory function. Please bring your reading glasses if required.

Exercise Monitoring
You may be asked to wear a wrist band activity monitor for a period of time (usually 5-7 days) to record your usual activity and sleep levels. We are interested in your normal pattern of activity so please do not defer from your usual regime.

Once the recording period is complete you can return the device by dropping it into your GP surgery or arrange home collection with the study team. The data will then be analysed and any clinically significant information relayed to your GP.

If you encounter any problems with the device, please contact the study team on 01865 228927 (08.00 - 16.30 Monday-Friday) - if we are not available, please leave us a message and we will return your call.

Ambulatory Heart Rhythm Monitoring
We may ask you to wear a device to monitor your heart rhythm and pulse rate. Again, please do not defer from your usual activities.

Once the recorded period is complete you can return the device by dropping it into your GP surgery or arrange home collection with the study team. The data will then be analysed and any clinically significant information relayed to your GP

If you encounter any problems with the device, please contact the study team on 01865 228927 (08.00 - 16.30 Monday-Friday) - if we are not available please leave us a message and we will return your call.

Health Registries
An important aspect of the study is to assess whether there is any difference in the health of people with VHD compared with those who don't have VHD. So we would like to use health registries to follow the health of participants enrolled in the study. Access to these registries allows us to find out information such as how many participants have been admitted to hospital or have had a heart attack. The registries we will be using are: the Office of National Statistics (ONS); the Health and Social Care Information Centre (HSCIC) databases including Hospital Episode Statistics (HES); and the National Institute for Cardiovascular Outcomes Research (NICOR) registries. HSCIC collect data relating to major diagnoses (eg cancer), as well as data on deaths. HES collect data about admissions to hospital, and NICOR collects information about heart attacks, coronary artery disease and heart valve disease in the United Kingdom.

All data from these databases will of course be entirely confidential. Participants anonymised data and images may be shared with commercial organisations, participants will not benefit financially from this.

Are there any possible risks from taking part?
Ultrasound scans are painless and safe. Unlike x-rays and other imaging tests, ultrasound does not use radiation. It has not been found to cause any problems or complications.

We will also take a blood sample. This may cause minor bruising at the site of needle entry but investigators are trained to minimise this possibility.

What are the possible benefits?
You are not likely to benefit personally from inclusion in this study, which aims to monitor the cardiac health of the Oxfordshire population in the long term.
You will be offered the opportunity to be approached for future participation in studies relevant to your health care status – this includes studies of healthy people in your age group.
We hope that by screening people using an echocardiogram, we will be able to improve our understanding not only of valvular heart disease, but also other cardiac conditions. This will help us to improve the screening and treatment of future patients.

What happens when the research study stops?
This study is a long term analysis of an Oxfordshire population. If at any point you wish to end participation in this study, please let us know and we can remove your contact details and even your study data measurements if you wish.

Will my taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. No personal data will be published at any time and your confidentiality is of the utmost importance to us. Data will be held in secure databases to which only authorised people will have access.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

What will happen if I don't want to carry on with the study?
You are free to withdraw from the study at any time. If you wish, we can then just make use of the information we already have about you. Alternatively, we can ensure if your samples and information are used for future research it is entirely anonymously, or we can destroy any identifiable samples or information we hold about you.

What if something goes wrong or I have a complaint?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (contact Dr Bernard Prendergast / Prof Saul Myerson using the details below). If you wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the John Radcliffe Hospital (contact Katie Harris, Head of Comments and Complaints, on 01865 223259) or the Complaints Office on 01865 221728, email complaints@ouh.nhs.uk. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Oxford University Hospitals (OUH) NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate). Compensation for any injury caused by taking part in this study will be in accordance with NHS indemnity.

What will happen to the data collected in this study?
If you take part in the study, this will be indicated on your medical records and your GP would also be informed. Some parts of your medical records and the data collected from the study would be looked at by authorised persons to check that the study is being carried out correctly. They may also be looked at by authorised persons from the NHS Trust. All investigators have a duty of confidentiality to you as a research participant and nothing that could reveal your identity would be disclosed outside the research sites.

Participation in future research
If you consent to be approached for involvement in future research, we will store your contact details separately from research data you have provided. Both your details and data will carry the same ID which can "link up" your details to your data. In this way we can identify research relevant to your particular healthcare status, and approach you appropriately. You can withdraw your consent to be contacted in the future at any time.

Involvement of your general practitioner
Your general practitioner (GP) will be informed of your participation in the study. With your permission, we will inform your GP of chance findings which arise from this research.

What will happen to any samples I give?
Blood samples will be retained in a secure environment for future analysis and will be stored in confidence under the custodianship of the Principal Investigator and an approved & regulated biobank / biosample storage facility. The samples may be used in future research as our understanding of blood markers grows. Future research may include genetic research (see below).

Will any genetic tests be done?
Yes, some samples may be used for genetic research into the causes of valve disease or other conditions. This research may be conducted by the study research team or collaborating research teams. As for study data, your samples will be stored separately from your other data but will carry the same linking ID. Genetic tests would look at common variations in genes with relation to healthcare status. We do not propose to test for inherited genetic diseases such as cystic fibrosis, or for conditions that will involve any other members of your family. The results of these genetic studies are very unlikely to have significant implications for you personally, but can provide important biological information about underlying disease processes.

What will happen to the results of the research study?
We anticipate that the results will be published in scientific journals for the benefit of the wider medical community. However, individual patients will not be identified in any publication and your personal and clinical details will remain strictly confidential. We may share our (fully anonymised) data with other carefully selected, ethically approved research studies. We believe that sharing of this data with other ethically approved studies would be greatly beneficial for future research. Any scientific publications arising from the study will be available on request to all participants. You will have no legal right to a share of any profits that may arise from the research.

Who is organising and funding the research?
OxVALVE is led by Dr Bernard Prendergast, Consultant Cardiologist at Guy's & St Thomas' Hospital, London and Professor Saul Myerson, Consultant Cardiologist at the John Radcliffe Hospital in Oxford. If you wish to know more about any aspect of the study, please contact the study team on 01865 228927.

The research is funded by the Oxford Biomedical Research Centre and The National School of Primary Care. Oxford University Hospitals NHS Foundation Trust is sponsoring this study.

Who has reviewed the study?
The Southampton and South West Hampshire Research Ethics Committee has reviewed and approved the study.

Where can I find independent information about taking part in research?
You can contact local branches of the NHS Patient Advisory Liaison Service (PALS). Here is their website: http://www.pals.nhs.uk/

Dr Bernard Prendergast Chief Investigator/Consultant Cardiologist OxVALVE Research Study Office Room B15, Level 0, Cardiac Investigation Annexe John Radcliffe Hospital Tel: 01865-228927 Fax: 01865-228989	Prof. Saul Myerson Principal Investigator/Consultant Cardiologist OxVALVE Research Study Office Room B15, Level 0, Cardiac Investigation Annexe John Radcliffe Hospital Tel: 01865-228927 Fax: 01865-228989 Web**:** www.rdm.ox.ac.uk/principal-investigators/researcher/saul-myerson

If you are concerned about any aspect of the study and feel the need for independent advice you are advised to approach your GP.