Wolfson Centre for Prevention of Stroke and Dementia
Nuffield Department of Clinical Neurosciences
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John Radcliffe Hospital
Oxford
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Information sheet

Study title: The Oxford Vascular Study (OxVasc)

You are being invited to take part in a 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 others if you wish. There will be an opportunity to ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The purpose of this study is to find out how common vascular disease (e.g. heart attacks, strokes, transient ischaemic attacks (TIA) and other circulatory problems) is in Oxfordshire and how it affects people's lives. This has never been done before for different types of vascular disease at the same time and in the same population. We hope the study will provide us with useful information on improvement in prevention and treatment and the best way of providing a service for those who suffer from these common problems. We hope we can build up a detailed picture of the way that people recover and the subsequent changes in health and memory over several years.

Why have I been chosen?

You have been chosen because you are registered with one of the eight GP practices in Oxfordshire which are collaborating in the study.

Do I have to take part?

It is up to you to decide whether or not to take part. This information sheet gives you more detailed information about the study. If when you have read this information sheet and you decide that you would be interested in taking part please complete and send back the expression of interest reply slip in the pre-paid envelope provided. A member of the research team in Oxford will then contact you to discuss participation, answer questions and discuss the next steps if you decide to go ahead.
If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

For all participants: If you decide to take part a member of the OxVasc study team would contact you and arrange a convenient time with you (during a week day) to take a verbal consent over the telephone. This will involve taking you through each point of the OxVasc

study consent and giving you time to consider these and to ask questions. A copy of the verbal consent form will be sent to you for you to keep.
The member of the study team would then undertake a telephone assessment of your health with you, which would take about 20-30 minutes. .

For those who have agreed to participate following circulatory problems there would be no further contact from the research team after this one telephone interview as part of the study.

If you have had scans of your brain, blood vessels and heart as part of your standard clinical care we would like to use these standard scans as part of this research. We would also like to gather some information on risk factors for vascular disease and other medical conditions from both your hospital and GP notes.

If you agree to participate in the study after a stroke or TIA:
You may also be invited for a clinic appointment at the Centre for Prevention of Stroke and Dementia (CPSD) at the John Radcliffe Hospital. All stroke clinics run at CPSD follow Oxford University Hospitals NHS Trust infection control guidelines. This would involve taking an extra sample of blood. This sample may also be used for future genetic research aimed at understanding the genetic influences on vascular disease but would not have implications for you personally.

If you are participating in the study following a stroke or TIA, this would involve being followed up by telephone, at home or in clinic by a researcher up to 3 times in the first year then at five years, ten years and twenty years or if any further vascular events occur.

In addition, if you are admitted to hospital for any other medical problem, one of our researchers may visit you whilst you are an inpatient to ask you some questions on your memory. All the information collected will be completely confidential.

What do I have to do?
This is an observational study and taking part in the study will not affect your current or future care. No new drugs or other treatments will be tested.

What are the possible disadvantages and risks to taking part?
If you are required to give a blood sample this may cause mild discomfort. There are no additional risks involved in taking part in this study.

What are the possible benefits of taking part?
We hope the information we get from this study may help us to treat future patients with vascular disease better.

What if something goes wrong?
The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Professor Peter Rothwell, Tel no: 01865 231603, email: peter.rothwell@ndcn.ox.ac.uk or you may contact the Research Governance, Ethics & Assurance Team (RGEA) University of Oxford, or the head of (RGEA), email: ctrg@admin.ox.ac.uk

Will my taking part in this study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it.
Responsible members of the University of Oxford and Oxford University Hospitals may be given access to data for monitoring and/or audit of the study to ensure we are complying with regulations.

What will happen to my data?
Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study, based in the United Kingdom, is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you, your medical records and also NHS Digital (for linkage between study data and civil registration data) using the minimum personally-identifiable information possible (name, date of birth and NHS number). We will keep identifiable information about you for ten years after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 25 years after the end of the study. If you agree to your details being held for future research, we will retain a copy of your consent form until such time as your details are removed from our database but will keep the consent form and your details separate.

The study team will use your name, NHS number, home address, and contact details to contact you about the research study e.g. to arrange follow-up visits, to make sure that relevant information about the study is recorded for your care, to oversee the quality of the study or to invite you for further research.

Data protection regulation provides you with control over your personal data and how it is used. 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.
Further information about your rights with respect to your personal data is available at
https://compliance.admin.ox.ac.uk/individual-rights

More information on how we use your data is available on our OxVasc website: *www.ndcn.ox.ac.uk/research/oxvasc*

If you are dissatisfied with the way we use your personal information, you have a right to raise any issues or lodge a complaint with the University of Oxford's compliance team at *https://compliance.admin.ox.ac.uk/individual-rights* or directly with the Information Commissioner's Office as a supervisory authority at:
https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/individual-rights/right-to-be-informed/

What will happen to the results of the research study?
It is likely that the results of this study will be published in medical journals after completion of the research. Results for participants will also be published on the study website and through local stroke groups and your GP surgery. If you decide to take part in the study, you will not be identified in any report.

What will happen to the blood samples I give?
Participants after Stroke or TIA: The blood samples you provide, as part of this study will be used for research purposes to understand more about risk factors for stroke and vascular events. The first blood sample you provide will also include genetic research aimed at understanding the genetic influences on vascular disease in general as well as on different types of stroke but will not have any implications for you personally.

To keep your information confidential your blood samples and any information recorded about you in this study will be 'de-identified' and assigned a study code. However, for genetic research your DNA is unique to you so it can never be completely anonymous.

Your anonymised blood samples will be used mainly by local researchers but ethically approved research projects may take place in hospitals, universities or non-profit institutions worldwide.
All blood samples will be stored in freezers in the laboratory at the Wolfson Centre for Prevention of Stroke and Dementia and if you agree to your samples being used in future research your consent form will be held until the blood samples are used up or destroyed.

Who is organising and funding the research?
This research is being organised by Professor Rothwell at the Wolfson Centre for Prevention of Stroke and Dementia, University of Oxford in collaboration with the Department of Primary Health Care, the Department of Cardiology and your participating General Practice. The study is funded by the Wellcome Trust and the NIHR Biomedical Research Centre, Oxford.

Who has reviewed the study?
The Oxfordshire Research Ethics Committee A has approved the study.

Participation in future research
In the future, we may invite you to participate in further studies which you may be eligible to join. If you agree to be contacted to consider these, your contact details would be held separately on a password-protected database in the Wolfson Centre for Prevention of Stroke and Dementia. All contact will come from the OxVasc research team in the first instance, and by agreeing to be contacted does not oblige you to take part in future research and you may request that your contact details are removed from the database at any time.

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: https://www.ouh.nhs.uk/patient-guide/feedback/pals.aspx

Contact for Further Information
If you would like any further information please ask the researcher who is discussing this information sheet with you or by contacting the Oxford Vascular Study Office on 01865 231601 or **email** orh-tr.oxvasc@nhs.net or https://www.ndcn.ox.ac.uk/divisions/cpsd

Thank you for reading this information sheet