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: CONTROLS

Study title: 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. 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 determine the causes of common vascular diseases (e.g. heart attacks, strokes, transient ischaemic attacks and other circulatory problems). Heart attacks and stroke are caused by diseased blood vessels and we know that some people are more likely to develop diseased blood vessels than others.

Risk factors such as smoking, high blood pressure and a family history of similar problems are known to be important in the disease process, but there is uncertainty about other risk factors. We will compare risk factors in people with vascular disease who are in the OxVasc study already with those from people from the local area who are not in the study ("controls") irrespective of whether they have had vascular disease in the past. We hope that this research will improve our understanding of the causes of vascular disease so that we can improve prevention and treatment.

Why have I been chosen?
You have been chosen because you are registered with one of the eight GP practices in Oxfordshire that are collaborating with us in the study and you have been proposed as a possible control by somebody who is already in the study.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to read and be asked to sign a consent form. You will be given a copy of the information sheet and signed consent form to keep. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?
If you decide to take part you would agree to an interview and have some simple measurements made by a study researcher (pulse, blood pressure, height, weight, and waist, hip and neck circumference) and take a sample of blood, in a clinic, at home or another place of your choice. The blood sample may be used for future genetic research

aimed at understanding the genetic influences on vascular disease but would not have implications for you personally. In addition, we will measure the blood flow in arteries in your head and neck with a non-invasive ultrasound probe, similar to those used in pregnant women before birth. We would also like to gather some information on previous blood pressure measurements and other risk factors for vascular disease from your GP notes. All the information collected will be completely confidential.
If you are invited to a clinic, these take place in the Centre for Prevention of Stroke and Dementia at the John Radcliffe hospital site and follow Oxford University Hospitals NHS Trust infection control guidelines.

What are the possible disadvantages and risks to taking part?
You will be required to give a blood sample from your arm, which might cause mild transient discomfort. There are no additional risks involved.

What are the possible benefits of taking part?
We hope that the information we get from this study will help us to improve the prevention and treatment of vascular disease better. Any previously unrecognised medical conditions, such as high blood pressure, that we find during the interview or examination will be explained to you so that you can have these assessed by your GP.

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 University of Oxford, Clinical Trials and Research Governance (CTRG) office at ctrg@admin.ox.ac.uk

Will my taking part in this study be kept confidential?
All information that is collected about you during the course of the research will be kept strictly confidential.

Responsible members of the University of Oxford 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 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. If you decide to take part in the study you will not be identified in any report.

What will happen to the blood sample I give?
The blood sample you provide as part of this study will be used for research purposes and will also include genetic research aimed at understanding genetic influences on vascular disease in general but will not have any implications for you personally.

To keep your information confidential your blood sample 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 sample will be used mainly by local researchers but ethically approved research projects may take place in hospitals, universities or non-profit institutions world-wide.

All blood samples will be stored in freezers in the laboratory at the Wolfson Centre for Stroke and Prevention and if you agree to your sample being used in future research your consent form will be held until the blood sample is used up or destroyed.

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 and 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 your recruitment to the study. 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 to be contacted regarding 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 make sure that relevant information about the study is recorded, 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 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/

Who is organising and funding the research?
This research is being organised by Professor Rothwell, 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 you might 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 your 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.

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 (telephone - 01865 231601).

Thank you for reading this information sheet.

PI: Professor Peter Rothwell
Oxford Vascular Study (OxVasc)Tel: 01865 231601 or email: orh-tr.oxvasc@nhs.net or go to https://www.ndcn.ox.ac.uk/divisions/cpsd/