Wolfson Centre for Prevention of Stroke and Dementia
Nuffield Department of Clinical Neurosciences
Wolfson Building
John Radcliffe Hospital
Oxford
0X3 9DU

Information sheet: All participants

Study title: The Oxford Vascular Study (OxVasc)- follow-up study (Phase 2)

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 find out the causes of stroke and TIA and how it affects people's lives. We hope the study will provide us with useful information on improvement in prevention and treatment and the best way of providing services and treatment for those who suffer from these common problems.

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, you have had symptoms of a stroke or TIA and you have been referred to the John Radcliffe Hospital for assessment.

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. 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?
During the visit, we will gather some information on risk factors for vascular disease from you and will review your hospital medical and GP notes. We also will record your blood pressure and assess your blood vessels in order to collect additional information for research. This will take approximately 15- 20 minutes.

You may be given a blood pressure monitor to take home with you to record further readings. An explanation of how to do this will be given to you by the researcher.

We will also take an extra sample of blood in clinic for research purposes which 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 have had a scan of your brain (magnetic resonance imaging–MRI or Computerised Tomography-CT and transcranial Doppler -TCD) as part of your standard clinical care, we would like to use these for research.

We would ask you to come back for a **clinic visit at one year** for a clinical examination and an interview on how you have recovered following your stroke or TIA.

We will provide travel expenses for any study visits to the clinic.

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?
This is a low-risk study and we do not think there are any risks to you if you take part. You will be required to give a blood sample which will cause mild discomfort. Where possible this blood sample will be taken at the same time as those collected for your clinical follow up. 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 stroke and TIA.

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 Research Governance, Ethics & Assurance Team(RGEA) office or the head of RGEA, email: RGEA.complaints@admin.ox.ac.uk

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study. Please call 01865 221473 or email PALS@OUH.nhs.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.

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, and 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 England (for linkage between study data and civil registration data for up to 20 years) using the minimum personally-identifiable information possible (name, date of birth and NHS number).

We will keep identifiable information about you for 10 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 to be contacted regarding future research, we will keep a copy of your consent until such time your details are removed from our database but will keep the consent form and details separate.
The study team will use your name, NHS number, home address, and contact details to contact you about the research study 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. If you decide to take part in the study you will not be identified in any report. Results for participants will also be published on the OxVasc study website and through local stroke groups and your GP surgery.

What will happen to the blood samples I give?
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 blood samples 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.

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 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.

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. email; oxvasc@ouh.nhs.uk or go to: https://www.ndcn.ox.ac.uk/divisions/cpsd/

Thank you for reading this information sheet.