Imperial College London

NHS Imperial College Healthcare NHS Trust

Participant Information Sheet

ACCESS@ICL:
An All-inclusive Cohort for the Comprehensive Examination of Sporadic Small Vessel Disease

REMOTE COHORT

Principal Investigator: Dr Alastair Webb
Sponsor: Imperial College London

You are being invited to take part in a research study. Before you decide whether or not to take part, 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. Talk to others about the study if you wish. Contact 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?

We can see the effects of chronic changes to the blood vessels deep inside the brain on a brain scan as people get older. This is called 'small vessel disease' but is present in the majority of older people and is often a feature just of ageing. However, when these changes become more severe they are one of the commonest reasons people have strokes, bleeds in the brain or develop dementia. However, we currently can't treat these changes as we don't fully understand why this happens, or what medications to use. This is partly because these changes vary a lot from one person to another.

This research study aims to improve our understanding of cerebral small vessel disease. In particular, we want to study a broader range of people with small vessel disease than in previous studies, how their brain scans differ and to continue to keep in touch with them to understand what medical difficulties they develop in the future.

Why have I been invited to take part?

You will have had an MRI or CT brain scan performed when you were previously an inpatient or attended an outpatient appointment at one of our hospitals. This has shown some evidence of these chronic changes that occur. This may be entirely in keeping with your age and is **not a cause for concern.** It may not have been mentioned to you as these changes are very common with increasing age. However, it means you may be suitable to join our research study to better understand how these changes occur and what they mean for people like you in the future.

Do I have to take part and can I withdraw?

No, it is up to you to decide whether or not to take part. If you do decide to take part, then you will be given this information sheet to keep and be asked to sign a consent form. Even if you decide to take part, you are still free to withdraw at any time, without giving a reason. If you decide not to take part, or withdraw from the study, this will not affect the healthcare that you receive, it will not affect your medical treatment and will not affect your legal rights.

What will happen to me if I take part?

You have been provided this information sheet to give you the information you need to consider whether you would like to take part. For you, the study involves allowing the research team to look at your medical records, and to use your medical data for research, including analysing any brain scans you have performed as part of your medical care, and any investigations you have had now and in the future to understand how people with different changes on a brain scan changes are different to each other, and whether this makes a difference to your future health. In addition, we would like to speak to you by telephone or video call now and in 1 year and 5 years time.

Each of these calls will involve us asking a bit more about what medical problems you may have had in the past, what medications you may be on and questions about your lifestyle such as whether you smoke, what you eat and drink and how well you sleep. Finally, we would ask you to do some tests down the telephone to measure how good your memory and thinking abilities are. If you are willing to, we may also ask if you would be happy to complete a more detailed assessment of your memory and thinking, carried out online but this assessment is optional.

The different groups of people in the study:

This is the group you are being invited to join now →

Remote Cohort

- **Includes** people with any of the features of 'small vessel disease' on a brain scan, even mildly, as seen in most people as they age.
- **Contacted by telephone** to ask for details of their medical history, lifestyle and to test thinking. Repeated after 1 and 5 years.
- Give permission for us to monitor their medical records.

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Core Cohort

- **Includes** people with any moderately-severe feature of 'small vessel disease' on a brain scan, which can be seen at any age.
- **Seen in person** for detailed testing of their medical history, thinking and mobility. Repeated at 1 and 5 years
- **Undergo extra tests** of control of their blood pressure and blood flow to the brain using ultrasound, lasting about an hour.

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MRI substudy

- **Includes** some core participants with mostly one feature on their scan.
- **Have an extra in-person visit** to have an extra research MRI scan to measure brain blood flow.

Cognitive substudy

- **Includes** people in the core cohort who volunteer for extra tests.
- **Stay for extra tests at their first visit** including detailed thinking and mobility tests, for an extra hour.

What are the possible disadvantages and risks of taking part?

The study is designed to understand how any symptoms you may have had are related to changes on your brain scan and your future health. As such, it is not specifically designed to improve your medical care. However, if we identify things that are important to reduce the risk of stroke and dementia, such as your blood pressure level and that these things are not fully controlled then we will write to your GP with this information. This may therefore help to reduce your risk of future problems, although identification of a medical concern may affect private medical insurance.

What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the condition that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

What happens when the research study stops?

A key aim of the study is to understand the long-term effect of the changes we measure at the baseline visit. Therefore, we will ask your permission to be able to access your medical records even after 5 years has passed, and to identify if you have had major medical problems or even died, whilst the study continues. If the permission to run the study continue to be granted, this may therefore continue for multiple decades. However, you can withdraw your consent at any time. If the study is stopped, then the data collected as part of the study will be retained for at least 20 years, except that any information that can be used to identify you will be removed.

What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Dr Alastair Webb, Clinical Reader in Stroke Medicine, Imperial College London). The normal National Health Service mechanisms are also available to you and you may contact the Imperial College Healthcare NHS Trust Patient Advice and Liaison Service (PALS) at 020 3312 7777 If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team.

What happens to my data?

Imperial College London is the sponsor for this study and will act as the Data Controller for this study. This means that we are responsible for looking after your information and using it appropriately. Imperial College London will keep your personal data for

- 20 years after the study has finished in relation to data subject consent forms
- 20 years after the study has completed in relation to primary research data.

The study is expected to finish in September 2034. For more information regarding the end date please contact the study team, see 'WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED' for contact information.

We will need to use information from you and your medical records for this research project. This information will include your name, NHS number, date of birth and contact details. People within the College and study team (see section sharing your information with others) will use this information to do the research or to check your records to make sure that research is being done properly and the information held (such as contact details) is accurate. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

As a university we use personally-identifiable information to conduct research to improve health care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

• Imperial College London - "performance of a task carried out in the public interest"; Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), Imperial College London relies on "scientific or historical research purposes or statistical purposes.

If the research team become aware that you have lost the ability to consent to the study whilst it is ongoing, most often due to the development of another medical condition that affects your thinking, we will ask a 'personal consultee' (someone who knows you well on a personal level and can advise on your likely wishes) to advise us whether they think you would wish to remain part of the study, and sign a consultation form to that extent. This would include continuing to keep and analyse your data and blood samples that we have already collected, and continuing to have access to your medical records and perform searches of centralised NHS and governmental records (for example death certification) to know if you develop further medical problems. In circumstances where no suitable person is available who can act as your 'personal consultee,' a 'nominated consultee' will be nominated in accordance with legal guidance who can advise on your likely wishes and is fully independent of the research project.

Will my GP be informed?

We will only contact your GP to inform them of your participation if we identify a medical reason to do so, or if we need to gather additional medical information only held by them.

International Transfers

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research. This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have, because some research using your data may have already taken place and this cannot be undone. If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records, your hospital or your GP. If you do not want this to happen, tell us and we will stop. This will not affect any healthcare or support you may be receiving separately.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of data collected. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to accessICL@imperial.ac.uk

Complaints

If you wish to raise a complaint about your experience of the study or any aspect of your medical care, please contact the research team first by sending an email to accessICL@imperial.ac.uk, or else you may contact the Imperial College Healthcare NHS Trust Patient Advice and Liaison Service (PALS) at 020 3312 7777

If you have concerns about how we have handled your personal data, please contact the research team first as above. Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

What will happen to the results of the research study?

The study is expected to result in research findings over many years, with some of the most important results only becoming available after we know what problems people run into in the long-term. We expect that the results of the study will therefore be disseminated by conference presentations, research publications in scientific journals, reports to regulators and funding bodies, through newsletters to participants and may be disseminated by press release or interview to mainstream media.

Who is funding the research?

ACCESS@ICL is funded by the combined support of a number of funders, including the Department of Brain Sciences, the St.Mary's Development Fund and philanthropic donations, and will require future funding from a range of funders.

Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS by the Essex Research Ethics Committee and Health Research Authority.

Contact for Further Information

If you wish to have further information about the study, please contact either the principal investigator (Dr Alastair Webb, alastair.webb@imperial.ac.uk) or at the study email address (accessICL@imperial.ac.uk).