Asymptomatic Carotid Surgery Trial (ACST-2)

ACST-2 Personal Data Privacy Notice

Data protection laws require researchers to inform participants of their rights and how researchers use participants data.

The 'data controller' for ACST-2 is the University of Oxford, which is responsible for deciding how any personal data collected during ACST-2 are processed.

We will respect the essence of the right to data protection and provide for suitable and specific measures to safeguard your fundamental rights and interests as set out in the relevant data protection laws. This means that we, as University of Oxford researchers are responsible for looking after your information and using it properly. The data can be lawfully processed under Articles 6(1)(e) and 9(2)(j) of the GDPR because the ACST-2 study is a task in the public interest and classed as research. The original consent that you provided for ACST-2 study participation allows us to process your confidential information under the duty of confidentiality.

To compare two ways of treating narrowed neck arteries that have not caused any (recent) symptoms. Specifically, patients who have either conventional surgery or stenting. We will measure stroke rates in both groups for at least five years

During your participation in ACST-2, you provide(d) personal data about yourself, such as information on your medical condition and medical history to your doctors at your local hospital and also to the ACST office in Oxford when you complete the Annual Questionnaire. Follow-up is achieved via annual questionnaires, supplemented with cause-specific civil registry mortality data. The UK is the only country to benefit from mortality data sourced from NHS. These data are entered into a computer system managed by the University of Oxford and stored securely. Only staff with appropriate training and permission can access this computer system.

As part of your participation in ACST-2, in addition to the information you provide about your health, the ACST-2 team in Oxford will ask for information about your health from NHS Digital. We will send your name, date of birth, NHS number and postcode to NHS Digital who can link this information to your centrally held records. NHS Digital provides information about study participants who have died, including the date and cause of death.

What will happen to information about me?

In ACST-2, personal data that directly identifies you such as your name, address, or date of birth (so-called "personal identifiers") will be used to link you with data held by NHS Digital – see section above. Such 'personal identifiers' will be held securely by the University of Oxford for up to five years after the scheduled end of the study (planned in 2025) to enable long-term follow-up of all participants until 2025 and further

contact with a smaller number of people (e.g. those who may have had a stroke) if considered necessary. Other than NHS Digital, we will not send these personal identifiers to anyone else and your data will not be used in any third countries or by international organisations. We will not use your data for the development of any automated decision making process, tool or application.

To help keep your information confidential, the information recorded about you in this study is 'de-identified', which means that your health information is labelled with a unique study ID number and not with your name. This means that you cannot be directly identified from the information.

Only this de-identified data will be used for the following purposes:

- analysis of the study results
- to help learn more about the best way to treat narrowed neck arteries to prevent stroke
- to write scientific articles on stroke prevention
- to help design and conduct future studies

It may be necessary for copies of the de-identified database to be shared with health regulators (such as the UK Medicines, Medicines and Healthcare products Regulatory Agency (MHRA) and Healthcare Regulatory Agency) and ethics committees, and other approved researchers. For example, if the MHRA have concerns about the safety of a particular carotid stent they may ask trials (like ACST-2) or registries to provide anonymised data relating to specific stents

The University of Oxford will keep all the study data and any research documents with personal information, such as consent forms, safely for at least a minimum of five years after the end of the study in line with the current University of Oxford guidelines.

What are my data protection rights?

If you decide that you do not want any new information about you to be collected and used for the study (known as 'withdrawal of consent'), please let the ACST-2 office know (see contact details below) and we will not collect any further information from you. All information that we have already collected will still be kept and used for the study.

You have the right to know what personal data the University of Oxford hold about you and to have a copy of those data. You also have the right to correct wrong or outdated personal data and request the deletion of your data. However, we may be obliged by law to keep your data to ensure consistency and reproducibility of the results and we cannot delete data that has already been used in analyses (please note that such analyses are run regularly throughout the study).

You also have the right to restrict or object to what we do with your data, or to request that your data be transferred elsewhere. However, your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data, as well as contact details

for the University's information compliance team (including the Data Protection Officer), is available at http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/

If you would like to exercise any of these rights or have other concerns about the way we have handled your personal data, please contact us; acst@nds.ox.ac.uk or **+44 (0)1865 617979** and we will work with you to try to resolve matters. You may also contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on **01865 616480**, or the head of CTRG, email ctrg@admin.ox.ac.uk

You may also lodge a complaint with the Information Commissioner's Office (telephone **0303 123 1113** or www.ico.org.uk).