Data Protection (GDPR) Privacy Notice

EASY-AS STUDY: A Randomised Controlled Trial of Early valve replacement in severe ASYmptomatic Aortic Stenosis

Information you need to know:

Symptoms of aortic stenosis (AS) can take years to develop, and some patients never develop symptoms at all. Patients who have symptoms can have the valve replaced, which works really well. However, as with any medical procedure, there is a chance of complications, and it can take a long time to recover.

Some heart specialists believe that replacing the valve before symptoms develop may be better than the conventional approach of performing the aortic valve replacement (AVR) once symptoms develop. However, the benefits of either strategy in patients with severe asymptomatic AS are unclear. The clinical assumption is that one strategy is not better than the other, but it remains one of the few areas of cardiovascular medicine where no randomised controlled trials have been performed

The EASY-AS study is managed by the Leicester Clinical Trials Unit (LCTU), which is part of the University of Leicester (UoL). The UoL is also the study Sponsor. Further information on the institution can be found here; https://le.ac.uk/ and on the unit website here; https://le.ac.uk/lctu.The UoL is the Data Controller for your information, in joint status with NHS Digital (England) and eDRIS (Scotland) for routinely collected health data and Sealed Envelope for randomisation data.

The Data Protection Officer is: Parmjit Singh Gill, Data Protection Officer, Information Assurance Services, University of Leicester, University Road,
Leicester, LE1 7RH. Email: dpo@leicester.ac.uk

This privacy notice explains how we use your personal information and your rights regarding that information.

What information are we collecting?

The type of personal information and the purpose for which is collected will depend on the specific research objectives of the research activity. The detailed information about data collected will be or has already been provided to you through the participation information sheet before you became a research participant.

We may collect information about you directly from you or on some occasions we may collect from third parties such as GPs or hospitals, when you have provided consent. The information collected will be proportionate to achieve the research objectives so our researchers will not collect more information than is actually needed.

The NHS will process your identifiable personal information such as your NHS number (England), Community Health Index Number (Scotland), gender, initials, date of birth and postcode will be collected as part of your baseline assessment and will be shared with NHS Digital (England) and eDRIS (Scotland), to obtain information about you from your electronic health care records. In the EASY-AS study we will collect the following personal information.

- Gender
- Initials
- Name of Participant - not applicable to all sites (electronic consent)
- Ethnicity (sensitive data)
- Health data (sensitive data)
- Date of Birth
- Date of Death
- NHS number (or equivalent)
- Pseudonymised data

There may be occasion where, with your approval, we will obtain the consent of a friend or family member to answer some follow-up questions on your behalf if you are no longer able to do so. In such instances we will collect their name only for the purposes of consent and all other details will stored by the hospital where their consent was obtained.

Why are we collecting your data?

We want to collect your data as part of this study, as it will be crucial in determining the benefits of two opposing approaches and will tell us whether patients with severe AS but no symptoms are better managed by early valve replacement rather than waiting for symptoms to develop. We also want to understand which option is most cost-effective for the health service because at present we do not know.

How we will use this data?

We will use pseudonymised data, for research such as collection of blood samples. We also use the pseudonymised data for auditing purposes.

Once the study has finished, 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.

Your name, initials and date of birth will be used as identifiers to ensure we are collecting the correct patient data.

Your NHS number, date of birth and gender will be used to access the NHS record linkage services. This will provide us with simple health information about you (such as medical events and hospital admissions) beyond the direct follow-up period of this study. Only those people mentioned previously, with the appropriate access, will see this personal data. Everyone else will only be able to identify you via your unique participant ID. All other data will be collected so we can see if any other criteria affects your treatment outcomes i.e. smoking history.

We will not use your data to record, learn or decide something about you as a patient.

The study involves allocating you to either Early AVR or Expectant Management. This will be performed using a web-based system called Sealed Envelope.

What is the legal basis for processing the data?

The legal basis for the processing of participant information that we are collecting and using for the study is Public Task as set out in the Data Protection Act 2018 and GDPR;

Article 6.1(e). Research is a public task that the University of Leicester performs in the public interest, and is part of its core functions as a University.

Where special category data will be collected, our additional conditions for processing information relies on;

Article 9.2(i); and that it is necessary for 'scientific research or statistical purposes' as set out in the Data Protection Act 2018 and GDPR Article 9.2(j).

If we are sharing your data with others who are we sharing it with?

Your personal data are collected by NHS research staff, managed by the University of Leicester and used to conduct the follow-up of this study. We will also be sharing pseudonymised data with the University of Southampton so we can conduct the health economics analysis.

Should you be approached to participate in the Patient Experience sub-study, we will share your name and contact details with the University of Sheffield with your permission. This is for the purposes of them being able to contact you regarding your interest in participating.

Progress reports and summarised research will be shared with the Department of Health and Social Care (DHS). The data shared with DHS will be in anonymised form (no identifiable data) and this is not caught under the data protection legislation.

How long we will process your data for?

This trial is expected to be completed by 31st March 2030. Unless a patient has agreed to participate in any future sub-studies or participants have expressed an interest in being invited to the results dissemination event and/or receiving a copy of the study newsletter, personal participant identifiable data will be retained for a maximum of 12 months following the end of the study, after which it will be destroyed.

Following completion of the study data analysis, data and essential study records, including the final study report, will be archived in a secure location for at least 15 years after the completion of the study, in accordance with LCTU Standard Operating Procedures. The data will be archived at a University of Leicester approved archiving facility which will ensure it is stored securely and only accessed by authorised individuals.

What are your rights and how to enforce them?

Under Data Protection legislation, you have rights in relation to the personal information we hold about you. These rights include:

- Right to withdraw consent – this is not absolute right. You can only exercise this right where NHS is processing identifiable data.
- Right to be informed
- Right of access - access your personal information
- Right of rectification - correct any inaccurate information
- Right to object or restrict

However, please note that some of these rights may be restricted if the exercise of these may seriously impair research outcomes. It is also important to understand that these rights will only apply if the research project holds identifiable information about you. Where your information has been completely anonymised, this information is no longer accessible and is therefore not classed as personal data for the purposes of the Data Protection Legislation. Therefore, the rights specified above apply will no longer apply.

How to complain to the Information Commissioner's Office?

The Information Commissioner can be contacted by the following methods:

- Post: **Information Commissioners Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.**
- Telephone: **0303 123 1113**.
- Email contact can be made by accessing www.ico.org.uk