University Hospital Southampton NHS
NHS Foundation Trust

RIPCORD 2

This is a PRIVACY NOTICE for patients who took part in the RIPCORD 2 study

Chief Investigator: Professor Nicholas Curzen, University Hospital of Southampton

1. Background

The RIPCORD 2 study was a collaboration between University Hospital Southampton (UHS) and Liverpool Heart and Chest Hospital (LHCH). The chief investigator and sponsor of the study are based at UHS. Patients were recruited into the study from 17 different hospital sites in the UK. The study compared two strategies for managing patients undergoing investigation for known or suspected problems in the heart arteries. Patients enrolled into the study were randomly assigned to either:

- Standard investigation undergoing coronary angiography ***alone***
  or
- Study investigation undergoing coronary angiography ***with pressure wire assessment*** *(a wire used to measure blood flow in the heart arteries)*

Patients were followed up for a period of 12 months after enrolment in the study which successfully completed enrolment of 1100 patients July 2018

2. Objectives

The RIPCORD 2 study assessed whether the routine use of pressure wire technology in the investigation of coronary artery disease would bring an overall benefit to patients and reduce healthcare costs. It was published in *"CIRCULATION"* an international, high impact journal in August 2022 and demonstrated no significant reduction in cost or improvement in quality of life between the two groups.

This was a major surprise because many observational studies had suggested that the use of pressure wire in this way did indeed have a major effect on these outcome measures.

It is possible, based upon longer term follow up from other similar randomised trials, that a difference in outcomes will emerge at longer term follow up. This is plausible because many clinical events, such as heart attack, death and requirement for coronary revascularisation, are attritional and increase over time. Thus, it is conceivable that the more accurate guidance in the group that assessed coronary anatomy and physiology would yield lower event rates and requirement for less tests and procedures than the angiography alone guidance in the other arm.

The RIPCORD 2 study now proposes to undertake long-term 5year remote follow-up of this cohort of study participants.

3. Data collection

The RIPCORD 2 study protocol was approved by a regional ethics committee. Participants were consented for involvement in the trial. A wide variety of data were collected from the patient and their case notes during the original hospital admission including details of procedures and treatments at that time.

Participants also gave consent for the study team to later acquire data from their electronic records, held by the NHS National Informatics Services (NHS Digital in England, NHS Wales Informatics Service in Wales, Public Benefit and Privacy Panel for Health and Social Care in Scotland). These data were collected with consent and formed an integral part of the reporting process for the main trial.

For the long term remote 5-year follow-up the study sponsor, UHS, will act as both the data controller and the data processor and will be the sole recipient of all patient data from NHS Informatics Services. UHS will request all hospital admission and mortality data for all patients in the RIPCORD 2 study starting from the date of the final participant follow-up at 12 months out to 5 years. The data set will be pseudonymised when sent from NHS informatics services to UHS and kept securely. All data analysis for the 5-year follow-up will be undertaken at the study sponsor site at Southampton.

This data linkage process is undertaken with s251 support provided by the Health Research Authority (HRA) on advice from the Confidentiality Advisory Group (CAG) as the common law legal basis, as the initial consent provided by study participants was not considered specific enough.

4. Database information

The databases of patients enrolled in the RIPCORD 2 study were collated and stored securely at LHCH during the study. In the longer term they will be transferred to the sponsor site at Southampton where they will be stored securely for up to 15years. Information gathered during the original hospital stay and subsequent data from quality-of-life questionnaires performed at one year, as well as the electronic healthcare data obtained from NHS informatics services is included in these databases.

5. Secure storage and processing of patient information

The data is currently stored securely in line with necessary standards set out in the Data Protection Act. All members of the research team accessing the data underwent the necessary training in the handling of personal healthcare/research data. The legal basis for processing the data is covered under General Data Protection Regulations (GDPR), Article 6 (1) (e) and Article 9 (2) (j). This means that data is being processed in the public interest for scientific/research purposes.

Personal data of patients (NHS/CHI number, date of birth, sex, and unique study ID) are securely stored at Southampton. These data were forwarded to NHS Informatics Service in England, Scotland and Wales, who control the Civil Registration Mortality (survival) and Hospital Episode Statistics (HES) data. These are considered personal data according to data protection rules (data protection act 2018, GDPR). The purpose of sending this personal data between Southampton and NHS Informatics Services is to link these data

together for the same patients, to provide accurate and complete information for researchers who can track a patient's journey through the NHS system.

NHS Informatics Services will securely transfer pseudonymised data to researchers at UHS. Pseudonymised means that identifying fields within a database are replaced with artificial identifiers, or pseudonyms so patient information can be processed without researchers being able to identify patients. All data processing will occur at UHS. All patient information will be stored on a secure network that is password-protected, and only accessible by those with specialised training and access for the duration of the study. The study will not use automated decision making or profiling.

The data will be stored by researchers at UHS until 2029 for analysis and dissemination purposes. All data will be published anonymously in peer-reviewed medical journals and/or presented at (inter)national medical conferences.

In terms of data processing, there is no change in the right for participants to access their data. Furthermore, GDPR does provide participants with additional rights including to: rectify their data; restrict processing, object to their data being processed and withdraw their data from being processed. However, it may not be possible for these rights to be granted in the case of a research study, please contact the research team (details at the end of this document) if you would like to discuss your data and how it is being processed. Participants are free to withdraw their consent at any time and no further data will be processed, however, it may be impossible to withdraw data already collected for the purposes of the study.

Please see the following link to the UK Information Commissioner's Office (ICO) for further information:

https://ico.org.uk/

University Hospital Southampton Data Protection:

UHS, as the data controller, is required by law to comply with data protection legislation. This hospital is committed to ensuring compliance with the data protection act and GDPR.

UHS processes the personal data of living individuals such as its staff, students, contractors, research subjects and customers. UHS has its own data protection and confidentiality policy (2022) as a commitment to the safeguarding of personal data processed by its staff and students, and to ensure compliance with the legislation. It is the duty of data controllers, such as UHS, to comply with the data protection principles with respect to personal data. This policy describes how UHS will discharge its duties in order to ensure continuing compliance with the Act in general and the data protection principles and rights of data subjects in particular.

Data Protection Officer UHS Contact Details:

Data protection officer
Trust Headquarters
University Hospital Southampton
Tremona Road
Southampton
SO16 6YD

Opting out

We are happy to discuss your rights to protect your data, and how exactly it will be used in our research. If you would like further information about the use of your data in this research study or would like to lodge a complaint to a supervisory authority – please contact us on the details given below or you can contact the UK Information Commissioner's Office (ICO): https://ico.org.uk/

If you would like to request that your patient information is not included in this study, please contact us.

Contact details (UHS):

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