University Hospital Southampton NHS
NHS Foundation Trust

RIPCORD 2

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

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Co-Principal Investigator Professor Rodney Stables, Liverpool Heart and Chest Hospital

1. Background

The RIPCORD 2 study is a collaboration between University Hospital Southampton (UHS) and Liverpool Heart and Chest Hospital (LHCH). The running of the trial is being coordinated by the ICECAP research team at 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 is comparing 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 would then be followed up for a period of 12 months after enrolment in the study. This would involve one contact around the 12 month point to complete a quality of life related questionnaire. Additionally, data will be collected electronically from NHS Informatics services in England, Scotland and Wales to capture information on subsequent hospital admissions, investigations and treatments occurring in the 12 month follow up period.

The study successfully completed enrolment of 1100 patients by July 2018. Since then the study team has been working on collecting follow up data to generate results of the study. The team is currently in the process of acquiring and analysing the electronic data necessary for this.

2. Objectives

The RIPCORD 2 study aims to assess 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.

3. Data collection

The RIPCORD 2 study protocol was approved by 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) . The team is currently in the process of obtaining and processing this data.

UHS and LHCH are joint data controllers and will also be processing the data. However, LHCH is the sole recipient of all patient data from NHS Informatics Services. LHCH have requested all hospital admission and mortality data for all patients in the RIPCORD 2 study (for a total 12 month period after each individual was enrolled in the study). The data set will have been pseudonymised when sent from NHS informatics services and will then be kept securely at LHCH. All data analysis will be performed at LHCH.

4. Database information

The databases of patients enrolled in the RIPCORD 2 study are securely stored at LHCH. It contains 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. All patients included in the database have been assigned a unique study number. No identifying data will be transferred out of LHCH after it has been received from NHS Informatics Services. No personal data will be transferred outside of LHCH, to any other country or international organisation.

5. Secure storage and processing of patient information

The data is stored securely in line with necessary standards set out in the Data Protection Act. All members of the research team accessing the data at LHCH have undergone 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 interests for scientific/research purposes.

Personal data of patients (NHS/CHI number, date of birth, sex, and unique study ID) is securely stored at LHCH. These data will be 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 LHCH and NHS Informatics Services is so that they can 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 data to researchers at LHCH; it will be pseudonymised. 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 LHCH. All patient information will be stored on a secure network that is

password-protected, and can only be accessed 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 LHCH until 2023 for analysis and dissemination purposes. All data will be published anonymously in peer-reviewed medical journals and/or at (inter)national medical conferences.

Addendum 4/11/22: We now plan to retain data until 2025. No new data will be collected on participants, and it will remain securely stored in the same location. The reason for the extended time of data retention is to allow us to answer any queries that may arise from the scientific community and perform further analyses after primary publication of the study.

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.

Liverpool Heart and Chest Hospital Data Protection:

LHCH is required by law to comply with data protection legislation. The UK's regulator for the legislation is the Information Commissioner's Office. It is the commitment of the hospital to ensure that every current employee and registered student complies with this Act to ensure the confidentiality of any personal data held by LHCH, in whatever medium. This Act came into force on 25 May 2018.

LHCH processes the personal data of living individuals such as its staff, students, contractors, research subjects and customers. LHCH has a data protection and confidentiality policy (2018) 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 LHCH, to comply with the data protection principles with respect to personal data. This policy describes how LHCH 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.

Further information may be accessed through the following LHCH link:

https://www.lhch.nhs.uk/about-lhch/information-governance/data-protection-and-confidentiality/privacy-notice/

or the following link to the UK Information Commissioner's Office (ICO):

https://ico.org.uk/

Data Protection Officer LHCH Contact details:
Wyn Taylor
Head of Information Governance and Administration
Liverpool Heart and Chest Hospital
Thomas Drive

Liverpool
L14 3PE
Wyn.taylor@lhch.nhs.uk

For additional contact details please access above LHCH link

University Hospital Southampton Data Protection:

UHS, as a joint data controller, is also required by law to comply with data protection legislation. This hospital is also 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 (2018) 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.

Further information may be accessed through the following UHS link:

https://www.uhs.nhs.uk/ClinicalResearchinSouthampton/Public-and-patients/How-we-use-personally-identifiable-information.aspx

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. (We would advise using the LHCH team as the primary means of contact for study related enquiries.)

Contact details (LHCH):

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