

# **The Distribution of Highly Sensitive Troponin in the Critically Unwell and Associated Mortality – one year follow up.**

**This is a privacy notice for patients who took part in the distribution of highly sensitive troponin in the critically unwell and associated mortality study**

**Duration: January 2020 – September 2021**

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**Chief Investigator:** Professor Nicholas Curzen

## **1. Research category**

The original study recruited 1,612 consecutive patients who underwent blood tests on admission to one of the three adult intensive care units for any clinical reason at University Hospital Southampton (UHS) between the 30<sup>th</sup> of January 2019 and 30<sup>th</sup> of July 2019. For each patient included within the study a single high-sensitivity troponin (hs-cTn) was added onto the first sample received during their intensive care admission. Subsequently hs-cTn testing was performed every day for the first two days and then every other day during the intensive care admission. This was performed to demonstrate the distribution of hs-cTn and the factors associated with elevated hs-cTn in intensive care. Furthermore the study aimed to assess whether there was an association between hs-cTn concentrations and inpatient mortality. This one year follow up study is an investigator-driven, retrospective, non-interventional, single centre study to assess whether a single hs-cTn result is predictive of future events, in particular adverse cardiovascular events. This was a planned follow up of the original study and received approvals from the research ethics committee (REC) and confidentiality advisory group (CAG) were received for the original CHARIOT study (IRAS 250338, REC 18/ES/0118, CAG 18/CAG/0156).

## **2. Background**

The data from the original study have provided useful insights into the distribution of hs-cTn in intensive care as well as the factors associated elevated hs-cTn levels. Furthermore the study has also suggested that hs-cTn may be a predictor of inpatient mortality.

We would like to assess whether the hs-cTn results are a predictor of a patients longer term prognosis. This would potentially allow the identification of groups of patients at higher risk of future events based on their hs-cTn results. These data would help to guide future investigation of potential medical interventions in similar groups to assess whether these interventions can improve outcomes in any high risk cohorts identified. This is particularly pertinent because at present we have relatively blunt risk assessment tools but the use of hs-cTn as a marker of increased risk may help to better provide tailored risk assessment for individuals.

### **3. Objectives**

The aim of this sub-study is to assess whether hs-cTn results taken during critical illness states have a long term prognostic role (at one year).

### **4. Data collection**

The original study protocol (which included the plan to assess one year outcomes) was approved by both REC & CAG, and is consistent with the International Conference on Harmonisation Guidance of Industry E6 Good Clinical Practice, the Declaration of Helsinki, and all local regulations. Consent was not sought due to the number of patients recruited, the importance of ensuring a consecutive cohort and because the study resulted in no changes to the patient pathway.

UHS will act as data controller, and will be sole recipient of all patient identifiable data. UHS will request mortality data at one year for all patients included within the original study from NHS Digital. The data set will then have all patient identifiable data removed and will be sent securely to the Keele Cardiovascular Research Group who will act as joint data processors with UHS.

### **5. Data base information**

The database of patients enrolled in the original study is securely stored at UHS. It contains baseline characteristics, markers of illness severity, the use of organ support, blood results and hs-cTn levels. This study is in the advanced stages of analysis and once completed will be published in respected medical journals and presented at medical conferences. All patients included in the database have been assigned a unique study number. Patient identifiable data relating to the unique study ID will only be available at UHS. UHS will request from NHS Digital the survival data at one year.

### **6. Secure storage and processing of patient information**

This study has already received REC & CAG approvals – processes designed to make sure researchers can benefit from accessing data while minimizing risk of any harm to patients - and Health Research Authority Confidential Advisory Group Section 2.51 approvals. The legal basis for processing the data is covered under General Data Protection Regulations (GDPR), Article 6 (1) (e) and Article 9 (2) (j).

Personal data of patients (NHS number, date of birth, sex, and unique study ID) is securely stored at UHS. These data will be forwarded, to NHS Digital, who control the Civil Registration Mortality (survival) data. These are considered to be personal data according to European data protection rules, GDPR. As UHS is running the study, they are called the data controller. The purpose of sending this personal data between UHS and NHS Digital is so that NHS Digital can link these data together for the same patients, to provide more accurate and complete information for researchers who can track a patient's journey through the NHS system.

NHS Digital will securely transfer pseudo anonymised data to researchers at UHS. Pseudo anonymised means that most 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. Finally, all pseudo anonymised data will be securely transferred from UHS to the Keele Cardiovascular Research Group (part of the University of Keele). Keele Cardiovascular Research Group are data processors and will work with UHS to analyse the data because they have particular expertise in the analysis of large cardiovascular databases. 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 data will be stored by researchers at UHS until 2021 for analysis and dissemination purposes. All data will be published anonymously in peer-reviewed medical journals and/or at (inter)national medical conferences.

This study will not use automated decision making or profiling. In terms of data processing, there is no change in the right for participants to access their data. Furthermore participants also have the right to: rectify their data; restrict processing, object to their data being processed and withdraw their data from being processed. In order to do any of these please contact the research team (details at the end of this document). Once the results have been published it will not be possible to remove them from the public domain and hence it will not be possible to withdraw consent at this stage. However, if requests for withdrawal are made after publication the patient's data will be removed from any unpublished work and the database.

## **University Hospital Southampton Data Protection:**

UHS 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 UHS, in whatever medium. This Act came into force on 25 May 2018.

UHS processes the personal data of living individuals such as its staff, students, contractors, research subjects and customers. UHS 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 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:

<http://www.uhs.nhs.uk/ClinicalResearchinSouthampton/Public-and-patients/Get-involved/General-Data-Protection-Regulation.aspx>

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

<https://ico.org.uk/>

### **Data Protection Officer Contact details:**

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

For additional contact details please access above UHS link

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

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