The short and long-term cardiovascular consequences of critical illness: The C3 study - Privacy Notice

The C3 study has 3 main aims:

1. To determine the short and long-term cardiovascular consequences of critical illness and identify in-ICU factors that affect them.
2. To identify the risk factors for new-onset atrial fibrillation/flutter occurring during critical illness.
3. To study the association between poor cardiovascular function during critical illness and long-term cardiovascular disease.

Context

The aim this study will be to find out which patients are at risk of heart attacks/strokes up to several years after discharge from an ICU. This study will also investigate whether treatments and events occurring in ICU contribute to this risk. Currently we are unable to identify which patients are at risk of heart attacks and strokes. We need to understand who is at risk. There are well-established treatments to avoid these conditions in the community. This research will help decide who should be considered for these treatments after critical illness.

Participants

This is a multi-centre UK study. Participating centres will be UK hospitals with digital Clinical Information Systems (CIS) running on their ICU, who are also ICNARC-registered sites. We will include adult patients admitted to an adult intensive care unit at one or more of the study sites between 2006 and 1st of August 2023.

This study is a retrospective long-term follow-up study that does not interact with patients or influence their care. This study requires a large number of participants / patient episodes in order to be able to answer the questions and objectives. It therefore is reliant on historic (retrospective) health records to reach its critical mass. As well as needing large numbers of records, the study would be weakened by any patients who were lost to follow-up (traditionally a significant limiting factor in long-term outcomes studies of survivors of critical illness). This study therefore requires access to these health records without individual patient consent, on the basis that the scale and data quality needed to answer its question would otherwise be reasonably unobtainable.

Follow-up / NHS Digital Linkage

All follow-up data will be collected from NHS Digital. This study does not interact with the patients themselves or their care in any way. We will be using ONS mortality data to collect cause and timing of death (as well as other demographics). HES will be used to collect information regarding your health problems before and after your admission to hospital. This will include medical problems that are either directly or indirectly associated with cardiovascular illnesses or critical illness in general.

This study has been reviewed and approved by Oxford Rec C (20/SC/0105).

Research is a task that we perform in the public interest. The University of Oxford, as sponsor, is the data controller. This means that we, as University of Oxford researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible.

The legal basis for the processing and storage of personal data for The C3 Study is that it is 'a task in the public interest' (article 6(1)(e)) and, that sensitive personal data is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes (article 9 (2) (j), based on Article 89(1)).

Your personal information (name, date of birth, NHS number and postcode – known as direct identifiers) will be used to register your study ID (a pseudo-anonymous unique number) with NHS Digital. This data exchange will occur between the hospital you were treated at and NHS Digital directly and in a secure manner. These direct identifiers will not be communicated with the study office at any time and not retained in the study database. The study office will hold the pseudo-anonymous study ID and other data from the time you were in hospital (such as lab records, treatments and drugs etc.). The study database will store a derivative of your postcode that is used to calculate social deprivation, which has been shown to be an important factor in healthcare.

Data that we receive and analyse from NHS Digital will be identified by a study ID only, and will not be identified by name, date of birth, NHS number or address. With the trial number, we will link to the original C3 Study database, and information collected during the earlier trial visits. The information received from NHS Digital will be imported into a database held securely by the University of Oxford and used solely for academic research purposes. Before analysing this complete dataset (including information already provided by trial participants with information from NHS Digital) personal identifiers will be removed. Importantly, whilst the information received is specific to each trial participant, no individual person will be identifiable in any publication arising from this work. Your personal data will not be shared with any 3rd parties and will not be used for any automated decision making or profiling. If you would like to have this data withdrawn, please contact the study team using the details given below.

Under Section 251 of the NHS Act 2006, we have permission to conduct this study without consent.

We have special permission to conduct the C3 Study without study-specific consent (i.e. link, transfer, process and analyse the data) from the Confidential Advisory Group. This permission is given under Section 251 of the National Health Service Act 2006 and its current regulations, the Health Service (Control of Patient Information Regulations 2002) (CAG reference number: 20/CAG/0038).

What to do next?

If you decide you do not want your data to be linked in this way you can withdraw from this follow-up, without affecting your current medical care, by contacting the study team, who would require your identifiers to then inform NHS Digital that you no longer wish to be part of the cohort. NHS Digital will not provide us with data for anyone who has withdrawn consent.

Data protection regulation provides you with control over your personal data and how it is used. When your health care information is being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.admin.ox.ac.uk/individual-rights or by contacting the study team using the details below.

If you have further questions or are not happy with the way your data has been handled, please contact the study team using the contact details below. Alternatively, you can contact the study sponsor on 01865 616480 or ctrg@admin.ox.ac.uk. You have the right to lodge a complaint with the Information Commmissioner's Office (0303 123 1113 or www.ico.org.uk.

Dr Robert Hatch

Critical Care Research Group

Kadoorie Centre

Level 3

John Radcliffe Hospital

Oxford

OX3 9DU

robert.hatch@ndcn.ox.ac.uk

01865 231456