Outcomes of Patients who survived Treatment on an Intensive Care unit for COVID-19 in England and Wales (OPTIC-19): a comparative retrospective cohort study – Patient notification

Why is this study being done?

Across England and Wales, over 10,000 patients have been treated for severe coronavirus disease 2019 (COVID-19) on an intensive care unit (ICU). Around 60% survived to leave hospital. We do not know how survivors' of severe COVID-19 infection, or the treatment they received on the intensive care unit, will affect their long-term health.

What is the purpose of this study?

The purpose of this study is to examine the risk of death and other adverse events (e.g. heart attacks and strokes) faced by patients who have survived treatment on an intensive care unit for COVID-19. Understanding what happens to these patients can help us make sure they receive suitable care from their GP and other NHS services after they leave hospital.

To do this, we will:

- Estimate the risk of death and other major health problems for patients in the year following hospital discharge
- Compare these risks to patients who survived to hospital discharge after treatment on an ICU for other illness in the three years prior to the emergence of COVID-19

Who is doing this study?

The study is being conducted by researchers at the University of Oxford, which acts as the sponsor for the research. It is a collaboration with researchers at the Intensive Care National Audit and Research Centre (ICNARC).

Who is included in this study?

This is a retrospective follow-up study of patients who were treated on an intensive care unit in England and Wales between January 2016 and July 2020. We will only include adult patients who were admitted to ICU as an emergency and survived to be discharged from hospital.

How will the study collect data?

This study will follow up survivors for 1 year after discharge from hospital using several different sources of patient data. We will also collect a list of health problem you had in the 5 years before your hospital admission (known as co-morbidities), to accurately measure what changes in your health occurred before and after your admission to hospital. By linking these different sources together, it will allow us to estimate a range of health risks

faced by survivors of severe COVID-19. We will compare these risks to patients treated on an ICU for other conditions.

Eligible participants will be identified from data collected by the Intensive Care National Audit and Research Centre (ICNARC). We will link these ICU data to records held by NHS Digital and other organisations to see whether these patients were readmitted to hospital and why. Information from the Office of National Statistics will allow us to know whether these patients died.

The study will use the following data sources:

- **Intensive Care National Audit and Research Centre (ICNARC)** – Case Mix Programme audit database
- **NHS Digital** – Hospital Episode Statistics (HES) Admitted Patient Care & Outpatients, Maternity Services Data Set (MSDS), Civil Registration (deaths), Emergency Care Data Set (ECDS), Hospital Episode Statistics Accident and Emergency, GPES Data for Pandemic Planning and Research (COVID-19)
- **Patient Episode Database for Wales (PEDW)**
- **UK Renal Registry (UKRR)**
- **National Institute for Cardiovascular Outcomes Research (NICOR)**
- **Stroke Sentinel National Audit Programme (SSNAP)**
- **UK Obstetric Surveillance System (UKOSS)**

How will the study process participants' data?

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.

Eligible participants will be identified from data collected by the Intensive Care National Audit and Research Centre (ICNARC). ICNARC will extract participants' personal information (date of birth, NHS number, postcode and gender – known as direct identifiers) and create a unique (pseudonymous) study ID. ICNARC will transfer the direct identifiers and unique study ID to NHS Digital and national audit databases to obtain follow-up data. This data exchange will occur in a secure manner. NHS Digital and other data providers will anonymise participants' data before transferring it securely to the study office at the University of Oxford. NHS Digital will remove any participants who have indicated that they do not wish their data used for research purposes (https://digital.nhs.uk/services/national-data-opt-out). No direct identifiers will be communicated to the study office at any time and will not be retained in the study database. The study office will only hold the pseudonymous study ID linked to ICU and follow-up data (e.g. subsequent hospital admissions). The study database will store information on eligible participants' local area, which has been derived from their postcode.

The pseudonymous data received from ICNARC, NHS Digital and other national audits will be imported into a database held securely by the University of Oxford and used solely for academic research purposes. Importantly, while the information received is specific to each study participant, no individual person will be identifiable in any publication arising from this work. Personal data will not be shared with any third parties (other than ICNARC) 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.

This study has also been reviewed and approved by Hampshire B Research Ethics Committee (21/SC/0021) and the Confidentiality Advisory Group (21/CAG/0017).

Can I request that my medical records are not used in this study?

Yes. If you decide you do not want your data to be used for this study you can withdraw at any time, without affecting your medical care. There are several ways to do this. You can register with the NHS Opt-out scheme (https://digital.nhs.uk/services/national-data-opt-out) to ensure your data are not used for research. You can also contact the study team (ccrg.research@ndcn.ox.ac.uk) or Chief investigator (peter.watkinson@ndcn.ox.ac.uk) directly to inform us that you do not wish your data to be used. We will require your identifiers to 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.

Your personal data is also protected by the General Data Protection Regulation and Data Protection Act 2018. Further details of these protections are given in the study Privacy Notice.

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