

The short and long-term consequences of critical illness on the heart and blood vessels

Submission date 03/09/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/09/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/09/2020	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Intensive care units (ICUs) support critically ill patients who would otherwise succumb to their acute illnesses.

Historically the benefit of ICU care to patients has been measured as survival. However, over the last three decades, survival of patients admitted to ICU has improved, so more attention is being focussed on the long-term health problems related to ICU care in survivors. Many of these problems significantly affect patients' lives. The associations with the ICU stay are poorly understood, partly because they can occur many years later.

This study will investigate one important group of conditions that are common after treatment on an ICU - strokes and diseases of the heart and blood vessels. Evidence from other countries suggests these may be more common after care on an ICU. Disturbances in the heart rhythm are also common during critical illness and separately contribute to the risk of heart attacks and strokes when they occur in the general population. We aim to study their long-term effects post critical illness.

The high number of strokes and heart attacks after ICU care may result from the patients' underlying illnesses that led to an ICU admission. This may also be due to long-term effects of ICU treatments for low blood pressure and poor circulation during critical illness. Heart problems occurring during an ICU stay such as abnormal heart rhythms may also increase patients' long-term risks.

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.

Who can participate?

Adult patients admitted to a general adult intensive care unit at one or more of the study sites between 01/01/2006 and 01/08/2023.

What does the study involve?
Patient records from 2006 to 2023 will be analysed.

What are the possible benefits and risks of participating?
None

Where is the study run from?
John Radcliffe Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2020 to August 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Robert Hatch, c3study@ndcn.ox.ac.uk
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

274165

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 274165

Study information

Scientific Title

The short and long-term cardiovascular consequences of critical illness: The C3 Study

Acronym

C3

Study objectives

The aim of 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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/08/2020, Oxford REC C (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8041; oxfordc.rec@hra.nhs.uk), ref: 20/SC/0105

Study design

Multicentre reterospective cohort study

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Major adverse cardiovascular events and arrhythmia

Interventions

This is a retrospective cohort study of major adverse cardiovascular events and arrhythmias in survivors of critical illness treated on an intensive care unit in the UK.

Intervention Type

Other

Primary outcome(s)

Measured using electronic healthcare records at 5 years post-discharge from ICU:

1. Mortality
2. Major adverse cardiovascular and vascular events
3. Arrhythmia

Key secondary outcome(s)

Hospital re-admission measured using electronic healthcare records at 5 years post-discharge from ICU

Completion date

01/08/2023

Eligibility**Key inclusion criteria**

Adult patients admitted to a general adult intensive care unit at one or more of the study sites between 01/01/2006 and 01/08/2023.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients that have informed their participating site that they do not wish their electronic records would be used for future research
2. Patients who inform us directly that they don't wish their records used in this research study

Date of first enrolment

01/09/2020

Date of final enrolment

01/08/2023

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

John Radcliffe Hospital

Oxford University Hospital NHS Foundation Trust

Headington

Oxford

United Kingdom

OX3 9DU

Sponsor information

Organisation

University of Oxford

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing statement:

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Data sharing agreements do not allow for the release of the data. The data will be held by the research group and requests for access will be considered on a case by case basis.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes