ISRCTN15905609 https://doi.org/10.1186/ISRCTN15905609

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

Registration date
10/09/2020

Overall study status
Completed

Last Edited
04/09/2020

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
Dr Jonathan Bedford, c3study@ndcn.ox.ac.uk

Study website
https://www.c3study.org

Contact information

Type(s)
Scientific

Contact name
Dr Robert Hatch

ORCID ID
http://orcid.org/0000-0002-8176-0831

Contact details
Kadoorie Centre
John Radlciffe Hospital
Headington
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 231456
c3study@ndcn.ox.ac.uk

Type(s)
Scientific

Contact name
Dr Jonathan Bedford

ORCID ID
http://orcid.org/0000-0001-9455-022X

Contact details
Kadoorie Centre
John Radlciffe Hospital
Headington
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 231456
c3study@ndcn.ox.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
274165

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available (retrospective study)

Health condition(s) or problem(s) studied
Major adverse cardiovasular events and arrhythmia

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

Intervention Type
Other

Primary outcome measure
Measured using electronic healthcare records at 5 years post-discharge from ICU:
1. Mortality
2. Major adverse cardiovascular and vascular events
3. Arrhythmia

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

Overall study start date
01/08/2020

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

Age group
Adult

Sex
Both

Target number of participants
80,000

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
England

United Kingdom

Study participating centre
John Radcliffe Hospital
Oxford University Hospital NHS Foundation Trust
Headington
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford

Sponsor details
University Offices
Wellington Square
Oxford
England
United Kingdom

OX1 2JD
+44 (0)1865 270000
ccrg@ndcn.ox.ac.uk

Sponsor type
University/education

Website
https://www.ox.ac.uk

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

Publication and dissemination plan
Multiple peer reviewed open access publications.

Intention to publish date
01/08/2023

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