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Critical illness consequences in terms of daily activity, sleep, exercise capacity, and feeling of fatigue

Submission date 25/01/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 31/01/2022	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/12/2024	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Many people who survive a severe illness leave the hospital with anaemia (reduced haemoglobin concentration), tiredness, poor quality of sleep, and disabilities in maintaining usual daily tasks.

Reduced blood oxygen-carrying capacity, also referred to as anaemia, is very common in critical illness survivors. With that in mind, the ABC Post-Intensive Care Trial aims to investigate whether anaemia correction by a red blood cell transfusion during the early period after intensive care could have a beneficial effect in terms of quality of life, physical activity, sleep, and heart and lung function.

Who can participate?
Adults who survived a life-threatening illness and were discharged from a general adult intensive care unit at the Royal Infirmary Edinburgh between 15/10/2021 and 01/02/2023.

What does the study involve?
In addition to getting routinely collected clinical and demographic data during intensive care unit and hospital admission. Each participant will be asked to:
1. Wear a wrist-worn accelerometer device (GENEActive) for an approximately 2-month period, ideally without taking it off, to measure activity and sleep.
2. Answer short, self-administered questionnaires. One focused on your perceived feeling of fatigue and the second on how independent you are in maintaining usual daily living tasks. Questionnaires will be administered twice, at the beginning and on the day of the exercise test.
3. Undergo a bicycle-based cardiopulmonary exercise test which is the most challenging part of the study and is likely to happen close to the date of the hospital discharge. This involves pedaling the stationary bike against gradually increasing pedal resistance till your maximal effort is reached. Various hemodynamic, cardiovascular, and pulmonary gas exchange variables will be recorded throughout the test.

What are the possible benefits and risks of participating?
There are no immediate benefits for the participants, but future clinical studies based on the

results of the current study might improve the quality of post-critical illness care.
Although the cardiopulmonary exercise test is a safe procedure, even in high-risk individuals, adverse events triggered by the exercise test such as sustained hypertension, arrhythmias, syncope, myocardial infarction, and even death exist. Fortunately, severe adverse events are extremely low and noted in less than 1% of tested people, with no death recorded in the UK.

Where is the study run from?
The Royal Infirmary Edinburgh (UK)

When is the study starting and how long is it expected to run for?
January 2020 to December 2024

Who is funding the study?
JSC “Center for International Programs” (Kazakhstan)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
286272

Protocol serial number
AC21012

Study information

Scientific Title
Anaemia & functional capacity, fatigue, daily activity, sleep, and circadian rhythm disruption among critical illness survivors

Acronym
ABC + Post-Intensive Care Study

Study objectives
Long-lasting health-related issues with almost all life domains affected and anaemia with undue fatigability as a frequent concomitant condition are often experienced after advanced critical illness requiring intensive care unit (ICU) admission. Little is known about cardiopulmonary

exercise capacity, reasons for exercise limitations, daily physical activity, and quality of sleep among this patient group during the interval from ICU to hospital discharge. Consequently, it seems reasonable to conduct a non-interventional clinical study aimed at:
1. feasibility of a cardiopulmonary exercise test within the given timeframe
2. feasibility of objective physical activity measurement by wrist-worn accelerometer device during a prolonged period of time
3. ascertain the level and dynamics of the feeling of fatigue and disability in daily living early after ICU

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/06/2021, East of Scotland Research Ethics Service (Tayside medical Science Centre, Residency Block Level 3, George Pirie Way Ninewells Hospital and Medical School, Dundee, DD1 9SY, UK; +44 (0)1382 383871; Tay.eosres@nhs.scot), ref: DL/21/ES/0051

Primary study design
Observational

Study design
Prospective single-centre cohort study

Study type(s)
Other

Health condition(s) or problem(s) studied
Cardiopulmonary exercise capacity, daily physical activity, quality of sleep, subjective experience of fatigue in critical illness survivors

Interventions
Current interventions as of 02/02/2023:

Any time after ICU, all eligible patients will be invited to take part in the study. The consented participants will be subjected to:
1. Wear an accelerometer device on the non-dominant wrist for consecutive 60 days
2. Complete both self-reported Visual Analog Scale - Fatigue and Barthel Index questionnaires
3. Optionally, undergo the bicycle-based cardiopulmonary exercise test at any point before the hospital discharge (only when a participant would be deemed to be able to perform the test)

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Previous interventions:

In the course of the first 7 days after ICU, all eligible patients will be invited to take part in the study. The consented to the study participants will be subjected to:
1. Wear an accelerometer device on the non-dominant wrist for consecutive 60 days
2. Complete both self-reported Visual Analog Scale - Fatigue and Barthel Index questionnaires
3. Undergo the bicycle-based cardiopulmonary exercise test at any point before the hospital discharge (only when a participant would be deemed to be able to perform the test)

Intervention Type
Behavioural

Primary outcome(s)
Feasibility outcomes measured using patient records at the end of the study:
1. Proportion of patients who completed the exercise test
2. Proportion of patients who completed an average duration of useable accelerometer recordings
Clinical outcomes:
1. Daily physical activity and quality of sleep variables are measured using a wrist-worn GENEActive accelerometer device for 60 days since enrolment
2. Functional capacity is measured by the bicycle-based cardiopulmonary exercise test (ramp protocol) before hospital discharge
3. Fatigue is measured using a visual analogue scale - fatigue (VAS-F) at enrolment and on the day of exercise test
4. Disability of daily living is measured using Barthel Index (BI) at enrolment and on the day of exercise test

Key secondary outcome(s)
1. Causes of exercise limitation among critical illness survivors inferred, based on the exercise test results analysis, and could be either cardiac, pulmonary, muscular, or general deconditioning at the earliest possible time point after ICU discharge
2. Age, gender, haemoglobin (Hb), inflammatory markers (CRP) concentration, and ICU-related factors such as disease severity (APACHE II; SOFA scores), length of mechanical ventilation, length of neuromuscular blocking agent used, total dose of glucocorticosteroids used, measured using patient records at the end of the study

Completion date
25/12/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 02/02/2023:

1. Patient older than 16 years.
2. Patient who required level 2 or 3 ICU care at any time point during the current hospital admission (defined as advanced respiratory support > 24h and/or at least two organ support)
3. Patient with an appropriate mental capacity to give consent for the study
4. Patient not involved in the post-ICU ABC trial and might have contraindications or objections to blood transfusion
5. Patient enrolled in the restrictive transfusion strategy group of ABC post ICU trial (Haemoglobin concentration at ICU discharge of >94g/L)
6. Patient enrolled in the liberal transfusion strategy group of the ABC post ICU study (Haemoglobin concentration at ICU discharge of >94g/L)

Previous inclusion criteria:

1. Patient older than 16 years.
2. Patient who required level 3 ICU care at any time point during the current hospital admission (defined as advanced respiratory support > 48h and/or at least two organ support)
3. Patient with an appropriate mental capacity to give consent for the study
4. Patient not involved in the post-ICU ABC trial and might have contraindication or objections for blood transfusion
5. Patient enrolled in the restrictive transfusion strategy group of ABC post ICU trial (Haemoglobin concentration at ICU discharge of >94g/L)
6. Patient enrolled in the liberal transfusion strategy group of the ABC post ICU study (Haemoglobin concentration at ICU discharge of >94g/L)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 Years

Sex
All

Total final enrolment
20

Key exclusion criteria
Current exclusion criteria as of 02/02/2023:

1. Active bleeding when screened
2. Primary neurological ICU admission diagnosis
3. Patients discharged from the ICU following cardiac surgery
4. Currently receiving or planned to receive end-of-life care
5. Not expected by a clinical team to survive to hospital discharge.
6. Patient with a proven chronic haematological disease that requires regular RBC transfusion to treat anaemia
7. Patient with dialysis-dependent chronic renal failure prior to ICU admission
8. Patient receiving regular erythropoietin (or any erythropoiesis-stimulating agent) treatment for anaemia prior to ICU admission.
9. Physical condition resulting in an inability to perform a cardiopulmonary exercise test (CPET), for example, major limb trauma, amputation, or primary neurological injury (eg. stroke, brain injury, Guillain-Barre syndrome).
10. Any absolute or relative contraindication for CPET testing.
11. Patient lacking mental capacity at the time of screening for eligibility
12. Patients with a major physical disability that severely affects the activities of daily living before ICU admission

Previous exclusion criteria:

1. Active bleeding when screened
2. Primary neurological ICU admission diagnosis
3. Patients discharged from the ICU following cardiac surgery
4. Currently receiving or planned to receive end-of-life care
5. Not expected by a clinical team to survive to hospital discharge.
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10. Any absolute or relative contraindication for CPET testing.
11. Patient lacking mental capacity at the time of screening for eligibility

Date of first enrolment
15/10/2021

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
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Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Organisation
NHS Lothian

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Government

Funder Name
JSC "Center For International Programs" (Kazakhstan)

Results and Publications

Individual participant data (IPD) sharing plan
Data sharing statement to be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 1.1	10/06/2021	31/01/2022	No	Yes
Protocol file	version 1.1	10/06/2021	31/01/2022	No	No
Protocol file	version 2.1	22/05/2022	02/02/2023	No	No