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Intensive Care Outcome Network Study - Phase 3

Submission date
24/07/2012

Recruitment status
No longer recruiting

Registration date
01/08/2012

Overall study status
Completed

Last Edited
26/11/2018

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Research on the effectiveness of intensive care treatment has mainly focused on how many patients survived their treatment. From this research we know that within the five years after intensive care treatment patients are more likely to die when compared to a general population of people of the same age and gender. Also, we know that intensive care unit (ICU) patients experience physical and psychological problems for a long time after discharge from an ICU. This study is gathering information from former ICU patients to try to identify the factors which are more likely to affect the risk of death or long-term physical or mental ill-health of ICU patients in the future. The ultimate aim of the study therefore is to try to improve the long-term quality of life of ICU patients.

Who can participate?
Patients who have been treated in the ICU at one of the hospitals taking part in the study are eligible to take part if they were at least 16 years of age when admitted to the ICU and experienced at least 24 hours of level three dependency care (ICU care) at any time during their hospital stay.

What does the study involve?
Patients who agree to help this study will receive a pack of up to six different questionnaires. Each questionnaire will take about 5 minutes to complete. Follow-up questionnaires will be mailed to participants at 12 months and 24 months after the date of discharge from the ICU.

What are the possible benefits and risks of participating?
There will be no direct benefits to patients taking part. However, we hope your participation will improve the care of patients treated in intensive care units in the future.

Where is the study run from?
Kadoorie Centre for Critical Care Research and Education at the John Radcliffe Hospital in Oxford (UK).

When is the study starting and how long is it expected to run for?
The study began in June 2012 and is expected to run for two years.

Who is funding the study?
The Bupa Foundation.

Who is the main contact?
Dr Duncan Young (Chief Investigator)
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Study website
http://www.iconstudy.org/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 2 - January 2012

Study information

Scientific Title
A study of the long term survival, psychological morbidity and health-related quality of life of patients discharged from Intensive Care Units in the United Kingdom

Acronym
ICON3

Study objectives

This study is a continuation of the ICON study (ISRCTN69112866) and its purpose remains the same, i.e. to generate a register of patients discharged from intensive care units (ICUs). The register will be used to study ICU treatment and its relation to mortality and long-term psychological morbidity, as well as changes in health-related quality of life over time after discharge from ICU.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central Berkshire, 23/06/2011, ref: 11/SC/0172

Study design
Observational multi-centre study

Primary study design
Observational

Secondary study design
Cross-section survey

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
Patient information sheet can be found at http://www.iconstudy.org/pages/relatives/Patient%20Information%20Sheet

Health condition(s) or problem(s) studied
Former intensive care patients of participating hospitals

Interventions
Postal questionnaires at 3, 12 and 24 months after ICU discharge

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Data from the ICON study will allow the identification of risk factors for poor long-term outcomes after patients have been treated on an intensive care unit, which will in turn inform the development of effective treatments and enable earlier recognition of factors related to poor long-term outcome in these patients. This entire process has the ultimate goal of improving the long-term quality of life of patients who have experienced treatment on an intensive care unit.

Secondary outcome measures
1. Obtain a response rate of 70% or more
2. To maintain the registry and database from ICON Phases 1 and 2
3. To determine the health-related quality of life of patients at three, twelve and twenty-four months after ICU discharge using SF-36 and EQ-5D and compare this with an age-, sex- and socio-economic status-matched historical control group
4. To determine the number of patients at risk of developing Post Traumatic Stress Disorder (PTSD) at three, twelve and twenty-four months after ICU discharge using PCL-C
5. To determine the number of patients at risk of depression and anxiety disorders at three, twelve and twenty-four months after ICU discharge
6. To assign a health utility index value to each of the first two survivor-years to allow calculation of quality-adjusted life years (QALYs) for all patients and those in specific diagnostic groups
7. To determine differences in health status for broad subgroups of patients based on diagnosis, and calculated (APACHE II and/or ICNARC score) hospital mortality risk
8. To determine the survival of these patients beyond two years after hospital discharge and so determine the relative risk of death over time of all these patients compared with an age and sex matched group drawn randomly from the UK population
9. To determine the relative risk of death over time for broad subgroups based on diagnosis, calculated hospital mortality risk (APACHE II and/or ICNARC score), sex, geography and socio-economic group (from postcodes) compared with the risk for all patients
10. To determine the relative risk of death for patients with a similar diagnosis but with or without a specific syndrome characterised by physiological changes (sepsis, ARDS etc)

Overall study start date
01/06/2012

Completion date
31/05/2014

Eligibility

Key inclusion criteria
1. Aged at least 16 years on admission to intensive care
2. Participants must have experienced at least 24 hours of level three dependency care (ICU care) at any time during their hospital stay and survived until the time of hospital discharge

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1000

Key exclusion criteria

1. Aged under 16 years
2. Unable to complete questionnaires and have no consultee to fill in the forms on their behalf
3. Foreign nationals
4. In residential care
5. In prison
6. Unwilling to consent
7. Life status cannot be traced (i.e. have no GP or NHS numbers)

Date of first enrolment
01/06/2012

Date of final enrolment
31/05/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Kadoorie Centre
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Joint Research Office
Churchill Hospital
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Sponsor type

University/education

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Bupa Foundation (UK) ref: 22095028

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/11/2018		Yes	No