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Intensive care unit outcome study

Submission date 14/03/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/05/2006	**Overall study status** Completed	
Last Edited 30/03/2017	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 7.0

Study information

Scientific Title
Intensive care unit outcome study

Acronym
ICON (Intensive Care Outcome Network)

Study objectives
The primary purpose of the study is to generate a register of patients discharged from intensive care units (ICUs). The registry 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)
Oxford Research Ethics Committee B, 12/04/2006, ref: 06/Q1605/17

Study design
Prospective longitudinal questionnaire-based study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Patients admitted to intensive care units

Interventions
Questionnaires regarding health-related quality of life (HRQOL).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
To start and maintain a register of patients discharged from hospital after being treated for greater than 24 hours in a participating ICU.

Secondary outcome measures
To evaluate in survivors of intensive care treatment:
1. Health-related quality of life
2. Risk of post-traumatic stress disorder (PTSD)
3. Major depression and anxiety incidence
4. Quality-adjusted life-years (QALYs)

Overall study start date
01/03/2006

Completion date
28/03/2013

Eligibility

Key inclusion criteria
1. All patients that survive to discharge from a participating ICU and remained on the ICU for greater than 24 hours
2. Patients aged 16 years or older on date of ICU admission

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1,000 per year; total of 4,000

Key exclusion criteria
1. Patients in non-participating ICUs
2. Patients admitted to a participating ICU who stayed less than 24 hours
3. Patients that do not survive to ICU discharge
4. Patients who are under 16 years old on date of ICU admission
5. Patients readmitted to an ICU and already entered in the ICON study will not have their new admission recorded

Date of first enrolment
01/03/2006

Date of final enrolment
28/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Oxford Radcliffe Hospitals NHS Trust (UK)

Sponsor details
Research and Development Office
Manor House
Headley Way
Oxford
England
United Kingdom
OX3 9DZ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Research organisation

Funder Name
Intensive Care Society

Alternative Name(s)

ICS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

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?
Protocol article	protocol	17/06/2008		Yes	No
Results article	results	27/03/2017		Yes	No