Intensive care unit outcome study

Submission date	Recruitment status No longer recruiting	Prospectively registered		
14/03/2006		[X] Protocol		
Registration date 02/05/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 30/03/2017	Condition category Other	[] Individual participant data		
30/03/201/	Other			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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)

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