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CESAR: Conventional ventilatory support versus extracorporeal membrane oxygenation for severe adult respiratory failure

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
07/12/2010

Condition category
Respiratory

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.cesar-trial.org/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 99/01/01

Study information

Scientific Title

Acronym
CESAR

Study objectives
The objective of this study is to test the hypotheses that, for patients with severe but potentially reversible respiratory failure, extracorporeal membrane oxygenation ECMO:
1. Will increase the rate of survival without severe disability by six months post randomisation.
2. Will be cost effective, compared to conventional ventilatory support.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Respiratory tract diseases: Severe acute respiratory failure

Interventions
Conventional positive pressure ventilation vs. Extracorporeal Membrane Oxygenation (ECMO)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Death or severe disability at six months. Severe disability will be defined as requiring full time nursing care at home, or continued residence in hospital.

Secondary outcome measures
1. Hospital Indices: duration of ventilation, length of ITU stay, length of hospital stay. Daily APACHE II score. In addition, data will be collected on ventilator settings, arterial blood gases, total intake minus output excluding blood loss and replacement, weight, full nutrition, haemoglobin, white blood cell count, blood products administered, prone position, nitric oxide, creatinine, bilirubin and maximum temperature. For ECMO patients only, data will be collected on mode (VV/VA), blood flow and sweep flow.
2. Follow up: Survivors will be contacted 6 months after randomisation for a detailed domicillary by a chest physician using a structured data collection form. Patients (or their carers, if necessary) will also complete questionnaires, assessment using standard scales to assess their activities of daily living, respiratory symptoms and psychological state.

Economic issues: The trial will assess the cost of treatment to the health and social services and to patients and their families in each treatment group. An incremental cost-effectiveness ratio will be calculated and compared to that for similar life-extending treatments. Information for the costs of inpatient and domicillary care will be collected using methods adapted from the neonatal ECMO Trial.

Overall study start date
01/07/2000

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Adult patients (18-65 years in UK)
2. With severe, but potentially reversible respiratory failure. Severe respiratory failure will be defined as a Murray score >3.0, or uncompensated hypercapnoea with a pH <7.20

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
180

Key exclusion criteria
1. Duration of high pressure and/or high FiO2 ventilation >7 days
2. Intra-cranial bleeding
3. Any other contra-indication to limited heparinisation
4. Patients who are moribund and have any contra-indication to continuation of active treatment

Date of first enrolment
01/07/2000

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Medical Statistics Unit
London
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Sponsor information

Organisation
Department of Health (UK)

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Quarry House
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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	23/12/2006		Yes	No
Protocol article	protocol	30/04/2008		Yes	No
Results article	results	17/10/2009		Yes	No
Results article	results	01/07/2010		Yes	No