

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

<b>Submission date</b> 25/04/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/12/2010	<b>Condition category</b> Respiratory	<input type="checkbox"/> 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

### 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

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 domiciliary 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 domiciliary 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 FiO<sub>2</sub> 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

United Kingdom

WC1E 7HT

**Sponsor information****Organisation**

Department of Health (UK)

**Sponsor details**

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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?
<a href="#">Protocol article</a>	protocol	23/12/2006		Yes	No
<a href="#">Protocol article</a>	protocol	30/04/2008		Yes	No
<a href="#">Results article</a>	results	17/10/2009		Yes	No
<a href="#">Results article</a>	results	01/07/2010		Yes	No