

Registration form

This form should be completed by a member of the intensive care team at the participating hospital.

STEP 1 - Collect registration data

Data necessary in order to register a patient for trial entry (please print clearly and be ready to give the information over the telephone).

<p>1. CESAR hospital code: <input style="width: 40px;" type="text" value="8"/><input style="width: 40px;" type="text" value="3"/><input style="width: 40px;" type="text" value="1"/><input style="width: 40px;" type="text" value="6"/></p> <p>2. CESAR hospital categorisation: RH</p> <p>3. Hospital name: Glenfield Transport Team</p> <p>4. Contact telephone number: _____</p>	<p>Please complete patient details or affix addressograph</p> <p>5. Patient's first name: _____</p> <p>6. Patient's surname: _____</p> <p>7. Patient's date of birth: <input style="width: 30px;" type="text"/><input style="width: 30px;" type="text"/> / <input style="width: 30px;" type="text"/><input style="width: 30px;" type="text"/> / <input style="width: 30px;" type="text"/><input style="width: 30px;" type="text"/><input style="width: 30px;" type="text"/><input style="width: 30px;" type="text"/> <small>dd / mm / yyyy</small></p> <p>8. Patient's gender: Male <input type="checkbox"/> Female <input type="checkbox"/></p>
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Please complete questions i-vii and go to Step 2 on the next page.

For each attempted registration, please record the recruiting doctor's name, the date and the time.

	Doctor	Date	Time		
i.(a) Duration of IPPV?	_____	_____	_____	_____	_____
i.(b) Duration of high pressure (>30cmH ₂ O) and/or high FiO ₂ (>80% oxygen)?	_____	_____	_____	_____	_____
ii. Is there intra-cranial bleeding? <small>(If yes, patient is not eligible for trial entry, at this time)</small>	Yes No <input type="checkbox"/> <input type="checkbox"/>	Yes No <input type="checkbox"/> <input type="checkbox"/>	Yes No <input type="checkbox"/> <input type="checkbox"/>	Yes No <input type="checkbox"/> <input type="checkbox"/>	Yes No <input type="checkbox"/> <input type="checkbox"/>
iii. Is there any other contra-indication to limited heparinisation? <small>(If yes, patient is not eligible for trial entry)</small>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
iv. Is there any contra-indication to continuation of active treatment? <small>(If yes, patient is not eligible for trial entry)</small>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
v.(a) PaO ₂ on 100% Oxygen	(mmHg) <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>
v.(b) PEEP	(cmH ₂ O) <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>
v.(c) Lung compliance	(ml/cmH ₂ O) <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>
v.(d) Number of quadrants with infiltration seen on chest x-ray?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
vi. pH (uncompensated hypercapnoea)	<input style="width: 30px;" type="text"/> . <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/> . <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/> . <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/> . <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>	<input style="width: 30px;" type="text"/> . <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/>
vii. Diagnostic category:					
1. Pneumonia					<input type="checkbox"/>
2. Obstetric acute respiratory distress syndrome (ARDS)					<input type="checkbox"/>
3. Other ARDS					<input type="checkbox"/>
4. Trauma including surgery within 24 hours					<input type="checkbox"/>
5. Other (please specify) _____					<input type="checkbox"/>

STEP 2 - Patient eligibility and bed availability

FORM A

Please now telephone 0116 287 1471 and ask the switchboard for the CESAR Trial Clinical Advisor. You will then be transferred to the CAT (Clinical Advisory Team). You will be asked to provide the information from Step 1. They will then call you back to let you know whether the patient is eligible and beds are available.

	Date	_____	_____	_____	_____	_____
	Time	_____	_____	_____	_____	_____
Is the patient eligible?	Yes		No		Yes	
Are beds available?	Yes		No		Yes	
Enter date and time beds are held until:	Date	_____	_____	_____	_____	_____
	Time	_____	_____	_____	_____	_____

If the answer to both of these questions is Yes, please continue with **STEP 3**, the assent procedure.

STEP 3 - Obtain assent

Please now talk to the relative(s) to tell them about CESAR and to seek their assent. Please give them a CESAR information pack* so that they have time to read the written information before being asked to sign the assent form.

* The CESAR information pack for relatives is kept in the CESAR trial folder.

Has assent been obtained? Yes No

If Yes, from whom? (name) _____ Relationship to patient? _____

If **NO**: please telephone 0116 287 1471 and ask the switchboard for the CESAR Trial Clinical Advisor. You will then be transferred to the CAT. They will then remove the reserve on the beds. You are not required to continue with this form. Please keep this form with the patient's notes.

If **YES**: please proceed to **STEP 4**.

STEP 4 - Collect randomisation data

Randomisation will be based on the current condition of the patient, therefore we will be repeating some of the questions from **STEP 1**.

i.(a)	Total duration of IPPV?	_____	(hrs)
i.(b)	Total duration of high pressure (>30cmH ₂ O) and/or high FiO ₂ (>80% oxygen)?	_____	(hrs)
ii.	Is there intra cranial bleeding <small>(If yes, patient is not eligible for trial entry, at this time)</small>	<input type="checkbox"/>	<input type="checkbox"/>
iii.	Is there any other contra-indication to limited heparinisation? <small>(If yes, patient is not eligible for trial entry)</small>	<input type="checkbox"/>	<input type="checkbox"/>
iv.	Is there any contra-indication to continuation of active treatment? <small>(If yes, patient is not eligible for trial entry)</small>	<input type="checkbox"/>	<input type="checkbox"/>
v.(a)	PaO ₂ on 100% Oxygen <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> (mmHg)	v.(b)	PEEP <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> (cmH ₂ O)
v.(c)	Lung compliance <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> (ml/cmH ₂ O)	v.(d)	Number of quadrants with infiltration seen on chest x-ray <input style="width: 30px;" type="text"/>
vi.	pH (uncompensated hypercapnoea) <input style="width: 20px;" type="text"/> . <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>		
vii.	Diagnostic category:		<input style="width: 20px;" type="checkbox"/>
	1. Pneumonia		<input style="width: 20px;" type="checkbox"/>
	2. Obstetric acute respiratory distress syndrome (ARDS)		<input style="width: 20px;" type="checkbox"/>
	3. Other ARDS		<input style="width: 20px;" type="checkbox"/>
	4. Trauma including surgery within 24 hours		<input style="width: 20px;" type="checkbox"/>
	5. Other (please specify) _____		<input style="width: 20px;" type="checkbox"/>
viii.	Number of organs failed?		<input style="width: 20px;" type="checkbox"/>

An organ can be considered to have failed if it meets the criteria set out on page 3, as defined by Moreno, R et al, Intensive Care Medicine 1999; 25:686-96.

STEP 5 - Randomisation

FORM A

Please telephone 0116 287 1471 and ask the switchboard for the CESAR Trial Clinical Advisor. You will then be transferred to the CAT who will ask for confirmation that assent has been obtained. They will ask you for the information provided in STEP 4. The CAT will then telephone the randomisation service to enter the patient into the trial.

Name of recruiting doctor: _____ Contact telephone number: _____

Apache II Score *

* Within 24 hours of admission to ICU, or at time of randomisation if this is less than 24 hours.

STEP 6 - Allocation

The CAT will then telephone you to inform you of:
(please write these in the appropriate spaces below)

Study number Allocation 1. Transfer for consideration of ECMO
2. Conventional ventilation

Date of randomisation / /
dd / mm / yyyy

Time of randomisation : 24 hour

If this hospital is a CTC and the patient is assigned to Conventional Ventilation please take a 'Level of Care and Organ Support' datasheet from the CESAR trial folder and collect the data on a daily basis. In all other cases the patient is being transferred and the CAT will give an estimated time of arrival of the transport team.

Please ensure the relative has a copy of the further information about the allocated treatment.

If randomisation has been successfully achieved please complete the details on Page 4. Make 2 copies and return 1 copy of the completed form to the CESAR Data Co-ordinating Centre and file 1 copy in the CESAR folder. Please keep the original with the patient's notes.

If the patient has not been randomised please keep this form in the patient's notes.

For the purpose of CESAR, the following definitions are being used.

An organ can be considered to have failed if it meets the criteria set out below as defined by Moreno, R et al, Intensive Care Medicine 1999; 25:686-96:

		Criteria met?	
		Yes	No
Respiratory:	$\text{PaO}_2/\text{FIO}_2 < 200$ mmhg with ventilatory support	<input type="checkbox"/>	<input type="checkbox"/>
Coagulation:	Platelet count $< 50 \times 10^3 / \text{mm}^3$	<input type="checkbox"/>	<input type="checkbox"/>
Liver:	Bilirubin > 102 mmol/l	<input type="checkbox"/>	<input type="checkbox"/>
Cardiovascular:	Dopamine > 5 mcg/kg/min (or adrenaline/noradrenaline any dose)	<input type="checkbox"/>	<input type="checkbox"/>
Central Nervous System:	GCS (Glasgow Coma Score) ≤ 9	<input type="checkbox"/>	<input type="checkbox"/>
Renal:	Creatinine > 300 mmol/l or urine output < 500 ml / day	<input type="checkbox"/>	<input type="checkbox"/>

Please complete this page only if a patient has been randomised to the CESAR Study.

FORM A

Identifying details

PATIENT

Surname: _____ Home address: _____
Forename: _____
NHS number: _____
(if available) _____
Telephone no: _____ Postcode: _____

NEXT OF KIN

Surname: _____ Home address: _____
(if different to patient's address): _____
Forename: _____
Relationship to patient: _____
Telephone no: _____ Postcode: _____

FAMILY DOCTOR

Full name: _____ Address: _____
Telephone no: _____
Postcode: _____

Please remember to post a copy of the assent form completed by the patient's relative when returning this form.

Please post a copy of this form to:
CESAR Trial Data Co-ordinating Centre, Medical Statistics Unit, London School of Hygiene and Tropical Medicine, Keppel Street, London WC1E 7HT using the freepost envelope which is provided in the CESAR trial folder.