

Step by step guide to recruiting a patient to **CESAR**

INCLUSION CRITERIA

- Adult patients (18-65 years)
- Severe, but potentially reversible, respiratory failure
- Murray Score ≥ 3.0 or uncompensated hypercapnoea with a pH < 7.2

STEP 1 - Registration (5 opportunities)

- Complete registration data on p.1 of registration form
- Tel. the Clinical Advisory Team (CAT) on **0116 287 1471** and ask for the CESAR Trial Clinical Advisor. Your first contact will be with the ECMO co-ordinator who will take a brief patient history
- The CAT will call you back. Please provide information from STEP 1 of the registration form

STEP 2 - Patient eligibility and bed availability

- The CAT will calculate the Murray Score and check bed availability, they will then call you

IS PATIENT ELIGIBLE AND BED/S AVAILABLE

YES

Please record the time bed/s are reserved until on page 2 of the registration form

NO

STEP 3 - Obtain assent

- Talk to relatives about CESAR in presence of patient's nurse
- Give relatives the CESAR information pack and allow as much time as possible before asking relative/s to sign the assent form

HAS ASSENT BEEN OBTAINED

YES

NO

- Tel. CAT on **0116 287 1471** and ask them to remove reserve on bed/s
- File Registration Form in patient's notes

STEP 4 - Collect randomisation data

- Collect data based on current condition of patient (page 2, STEP 4 of registration Form)

STEP 5 - Randomisation

- Tel. CAT on **0116 287 1471** and ask for the CESAR Trial Clinical Advisor
- Confirm assent has been obtained
- Give information from STEP 4 of registration Form (page 2)

STEP 6 - Allocation: The CAT will call you back

- Please enter details of **allocation, study number** and **date/time of randomisation** onto the Registration Form (page 3)
- Inform relative/s, named nurse and patient's nurse of the allocation and ensure relative/s has a copy of the appropriate information leaflet following allocation
- Complete page 4 of the Registration Form
- Make **2 copies** of the Registration form. Send one copy to the CESAR Data Co-ordinating Centre with a copy of the signed assent form, file the second copy in Section 2 of the Trial Folder and keep the original in the patient's notes.

If the patient is being transferred:

- Inform relative/s of the estimated time of arrival of the transport team
- The transport team will gain assent for the transport and ECMO (if allocated)

EXCLUSION CRITERIA

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

DO NOT REGISTER THE PATIENT