

CESAR Clinical Co-ordinating Centre
Glenfield Hospital NHS Trust
Groby Road
Leicester LE3 9QP

tel: 0116 250 2423 (office) or 0116 287 1471 (switchboard)
fax: 0116 250 2374 website: www.cesar-trial.org



Conventional Ventilation or
ECMO for
Severe
Adult
Respiratory Failure

CESAR and the Emergency Inclusion Protocol

What is CESAR?

CESAR stands for Conventional ventilation or ECMO for Severe Adult Respiratory failure. It is a nation-wide multicentre randomised controlled trial which aims to compare a strategy of transfer of patients for consideration of ECMO with continued conventional ventilation. Adult patients (18-65) with severe but potentially reversible respiratory failure are eligible for the trial. Severe respiratory failure is defined as either a Murray score of >3.0 (see appendix 1) or hypercapnea with a $\text{pH} < 7.20$.

What are the contra-indications to CESAR trial entry?

- Duration of high pressure and high FIO_2 ventilation > 7 days.
- Severe trauma within the last 24 hours, intra-cranial bleeding and any other contra-indication to limited heparinisation.
- Patients who are moribund and have any contra-indication to continuation of active treatment.

How do patients normally enter the study?

Usually patients are referred from hospitals that are registered with the trial and have obtained approval from their local research ethics committee (LREC). Once the Clinical Advisory Team in Glenfield, Leicester has determined that the patient is suitable for the CESAR trial then assent is obtained from the relatives and the patient is randomised either to ECMO or continued conventional ventilation. If the patient is randomised to ECMO the ECMO transport team will come and transport the patient back to Leicester. If the patient draws conventional treatment then the subsequent course of treatment for the patient is determined by the type of hospital that the patient is in. If the patient is in a Conventional Treatment Centre (CTC) then they will receive their conventional ventilation without moving. CTCs are larger hospitals with well-developed ICUs. If, however, the patient is in a smaller ICU (referring hospital, RH) then they will be transferred to a CTC for their conventional ventilation. The ECMO transport team will carry out the transfer. This is to ensure that patients receive equal intensity of treatment in both arms of the trial.

What is the Emergency Inclusion Protocol (EIP)?

- The Clinical Advisor at Glenfield has already discussed your patient with you.
- You will have received the Introductory Information and a cover letter for relatives, the summary protocol, Murray Score, agreement to become a CESAR trial centre and this document by fax.
- Your hospital will be granted emergency RH status.
- You must agree to become a CESAR trial centre, by discussing with your hospital manager, signing and returning the agreement form by fax to 0116 2502374.
- Once you have done this the ECMO transport team will come and assess your patient.
- The transport team will discuss CESAR with the patient's relatives in the presence of the patient's nurse.
- The relatives will be given time to consider the study with time to talk to the nurse before being asked to give assent.
- If your patient is suitable they will complete the trial entry procedure.
- If your patient draws conventional treatment they will be transferred to the nearest available CTC.
- If your patient draws ECMO they will be transferred to Glenfield.

I want my patient to have ECMO, but I do not want them entered into the CESAR trial

ECMO will not be available outside the framework of the trial.

If you have other concerns that are not answered by this document please contact the CESAR Clinical Advisory Team at Glenfield on 0116 2871471.