



Conventional Ventilation or ECMO for Severe Adult Respiratory Failure

INTRODUCTORY INFORMATION

You will know from talking with the doctor that your relative has very serious breathing problems. This must be an extremely anxious time for you. Nevertheless, we would be grateful if you would take a little time to read this leaflet. It asks you to think about allowing your relative to join an NHS study which is taking place in many hospitals in the UK. Whilst, legally, only your relative can give consent to take part, we would not include your relative without your agreement.

What is the study trying to find out?

Unfortunately, because of the seriousness of the problem that your relative has, many patients do not recover. This study is comparing two ways of looking after patients with serious breathing problems.

- One way uses a ventilator to push oxygen into the lungs. We call this conventional ventilation as it is the most common method.
- The other way uses a system called ECMO to by-pass the lungs. This is only available in one place (Leicester), and only available for this study.

At this time, we do not know if conventional ventilation is better or worse than ECMO for patients with serious breathing problems. This study is designed to help decide the best way of caring for patients with these problems so that more patients survive. It involves the co-operation of many doctors and nurses in hospitals throughout the UK.

What is already known about treatments for patients with severe breathing problems?

Conventional ventilation

Your relative is already on conventional ventilation. This form of care is currently considered the best standard care, and has been used for many years. This means that the staff in large intensive care units are very experienced in using it. However, using a ventilator to give oxygen at high pressure over a long period of time causes some lung damage to patients who already have breathing problems.

ECMO (Extra-Corporeal Membrane Oxygenation)

ECMO involves an operation (under anaesthetic) to set up a temporary by-pass for the patient's lungs. While on ECMO, patients stay on very gentle ventilation which may help the lungs recover. Glenfield Hospital in Leicester is the only UK hospital with a reasonable length of experience in using ECMO for adults, so patients may have to be transferred some distance. Transferring very ill

patients may be risky, but despite this ECMO may well be helpful. The early results of using ECMO appear promising. However, we are not yet sure whether ECMO is better or worse than conventional ventilation. So while it is being investigated, ECMO is only available in this study.

What would being in the study involve?

If you decide to agree for your relative to take part, then the next stage is to find out which of the two treatments will be offered.

- Half the patients in the study will continue to be treated on a ventilator. If your relative is assigned to receive conventional ventilation then transfer to a larger Intensive Care Unit will be arranged. This is to ensure that your relative is in a centre that can offer all types of specialist conventional treatment, which presently may not be available.
- The other half will be transferred to Glenfield Hospital, Leicester to be considered for ECMO.

Once your relative is in the study, neither you nor the doctor will be able to choose which of these two methods will be offered. Which treatment is offered will be decided by chance, rather like the toss of a coin. This element of chance is important so that the two methods can be tested fairly. The doctor will call a central office and will be told which of the two treatments will be given. The doctor will, of course, tell you this straightaway, and give you more detailed information about it.

If your relative is to have conventional ventilation, then your relative will be cared for in a larger Intensive Care Unit which can offer the most advanced types of conventional ventilation. Your relative will be transferred to the nearest such unit with a suitable bed available, so that he/she can receive the best possible intensive care and conventional ventilation. Most hospitals offer accommodation for relatives. The staff at the new hospital will be able to provide details when you arrive.

If your relative is assigned to have ECMO, then transfer to Leicester will be arranged. You may wish to go to Leicester too, where free accommodation is provided for relatives. Transport costs can be discussed with staff if these are a problem.

Whatever treatment your relative is offered, an experienced transport team will come to transfer your relative. The quickest and safest type of transport will be arranged for your relative. This usually means either an ambulance or a helicopter.

If your relative improves and is able to come off the ventilator or ECMO and discuss their illness, the doctors will explain about this study. We will send written information to your relative when discharged home. Your relative may, of course, choose to leave the study at any time.

Your relative and others closely involved will be asked to complete short questionnaires. We plan to follow up all patients in this study. If your relative agrees to continue in the study, then we will inform the GP. A home visit will be arranged for about six months ahead. A researcher working with this study will assess your relative and will also collect information on events related to your relative's health. The researcher will not be medically qualified, but will be professionally qualified to undertake the assessment. Of course, all information that we collect from health service notes and directly from the patient or relatives will be treated in the strictest confidence.

Thank you for reading this at such a distressing time. Please feel free to discuss this study with members of your family or someone else before you make a decision. The staff who have given you this information will be pleased to answer any questions you have about what it means to take part in this study and the two forms of treatment.

Does participating in this study affect my relative's rights under the Patients' Charter?

No! Your relative is still protected by the Patients' Charter,

and has the same rights to register complaints or receive compensation that all NHS patients have, at all times.

What if something goes wrong?

If your relative is harmed by taking part in this research project, there are no special compensation arrangements. If your relative is harmed due to someone's negligence, then he/she may have grounds for legal action but he/she may have to pay for it. Regardless of this, if your relative wishes to complain about any aspect of the way he/she has been approached or treated during the course of this study, the normal health service complaints mechanisms may be available to him/her.

Your decision

We would like to give you more time to think about this but as your relative is so ill you will need to decide very soon in order that we can begin to make the necessary arrangements.

- If you decide not to include your relative in the study, your relative will still get the best possible conventional ventilator care in this hospital.
- If you do decide to include your relative in the study, then your relative will be transferred to a specialised centre to have either conventional ventilation or ECMO.
- Whatever you decide, your relative will not get any care that is known to be worse than another.

When will we know the results of the study?

The results of the study will not be ready before the end of 2004.

What if I have other concerns?

If you have any problems, concerns or other questions about this study, you should preferably contact the local investigator at this hospital first:

DOCTOR

TELEPHONE

If you have any complaints about the way the investigator has carried out the study, you may contact:

DOCTOR

TELEPHONE

The doctors involved in the study are not being paid to recruit patients and the CESAR study is funded by the NHS Research and Development Health Technology Assessment Programme.

Please see the accompanying leaflets:

Information for relatives if allocation is to conventional ventilation and **Information for relatives if allocation is to ECMO** for further information.

Key points

- Your relative has serious breathing problems and is on conventional ventilation.
- ECMO (Extra-Corporeal Membrane Oxygenation) may help the lungs recover.
- But ECMO is only available at Glenfield Hospital in Leicester, so your relative would need to be transferred.
- If you agree for your relative to take part in the study he/she will be randomly assigned either to be transferred to a large Intensive Care Unit to continue on conventional ventilation or to be transferred to Leicester for ECMO.
- Information for the study will be collected from your relative's clinical notes and others closely involved.
- Information about the study will be sent to your relative at home on discharge from hospital.
- If your relative agrees, a researcher will make a home visit in about 6 months time.



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