



**Conventional Ventilation or  
ECMO for  
Severe  
Adult  
Respiratory Failure**

## **INFORMATION FOR RELATIVES IF ALLOCATION IS TO ECMO**

As you know, your relative is very ill with breathing difficulties. Unfortunately this is a very serious problem and many patients do not recover from it. There is an urgent need for new treatments. These have to be compared with the treatment that is normally used to make sure we only introduce new treatments that are a real improvement. The aim of the CESAR study is to find out whether a new treatment, ECMO, may help patients with such severe breathing problems so that more patients survive. At this time we do not know if ECMO is better or worse than conventional ventilation for patients with serious breathing problems.

Your relative has been allocated to the ECMO treatment group. This decision was made at random, so that the methods can be tested fairly. This leaflet provides written information about ECMO for you to keep. It is not meant to replace any discussions you have with the doctors and nurses looking after your relative. Staff at this hospital and at Glenfield Hospital in Leicester are happy to discuss any points you want to have repeated, or given in more detail. Please feel free to ask any questions whenever you want.

### **What is ECMO?**

ECMO for adults is a new treatment for severe respiratory failure and it is only used in Glenfield Hospital in Leicester. ECMO stands for Extra-Corporeal Membrane Oxygenation. This means that an artificial lung (the membrane) oxygenates the blood outside the body (extra-corporeal). The ECMO machine is very similar to the heart-lung machines used to keep patients alive during open-heart surgery (see the diagram on page 4). Glenfield Hospital in Leicester is one of the most experienced ECMO centres in the world, and is the only hospital in the UK that is very experienced in using ECMO for adults.

### **Does ECMO work?**

While it is likely that ECMO works, it is unclear whether it works better than conventional ventilation. This is what this research will find out. Much of the early experience with ECMO has been with babies and children. A few years ago a study was made of ECMO use for new-born babies. These babies had developed severe breathing problems. The study was very like this one. Babies were randomly allocated to either receive continued conventional ventilator treatment, or to receive ECMO. They were treated at one of five hospitals in the UK skilled in doing ECMO for babies (of which Glenfield was one). More babies survived when ECMO was used than when a conventional ventilator was used. Obviously, adults' lungs are very different from those of babies, but the early results of ECMO treatment in adults are also promising. However, we do not as yet

have enough information to be sure whether ECMO or conventional ventilation is the better treatment for adults with severe respiratory failure.

### **Why can't my relative have ECMO at this hospital?**

ECMO treatment requires a lot of specialised equipment and specially trained staff. In order to make the best use of both the equipment and staff they are concentrated in one place. This makes sure that the staff keep their skills in using the equipment safely as they are using it every day. This means that in order to receive ECMO your relative must be moved to Leicester. Obviously, there is a certain risk associated with moving a patient who is so severely ill. However, in our previous experience almost all patients can be moved safely, and we will do everything to make sure that the transfer is as safe as possible. A team from Glenfield Hospital will arrive soon to take your relative to Leicester. We appreciate that you cannot always be at your relative's bedside, but it would be very helpful if you could be available when the transport team arrives. Please check with the nurse caring for your relative to find out when they are due.

### **What will happen when the transport team arrives?**

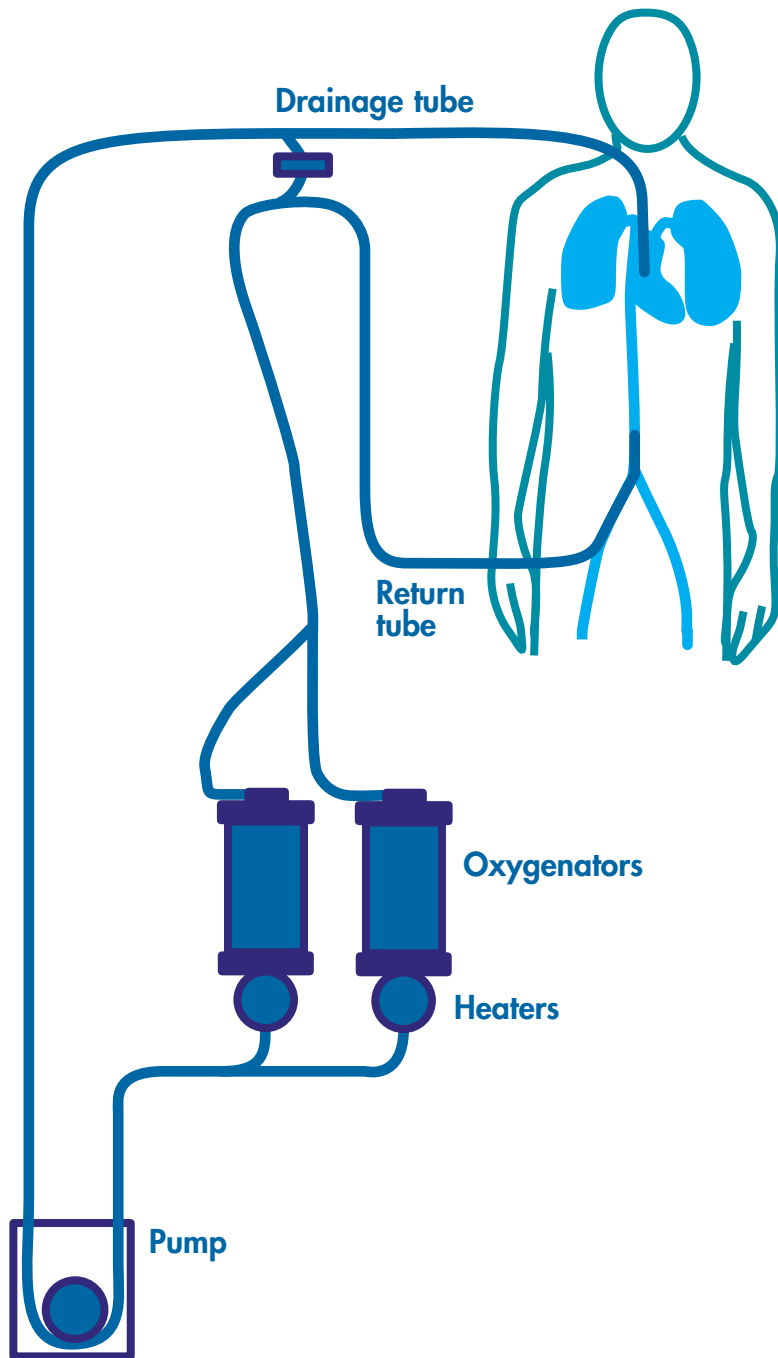
The doctor and nurse from the Leicester transport team will carefully examine your relative. Then they will make preparations for transfer back to Leicester. This may mean travelling by helicopter, if they think this is the safest method. If the transfer is by road we strongly advise you not to try to follow directly behind the ambulance. This can be very dangerous. A map and directions for travel to Glenfield Hospital are included on the back page of this leaflet.

The transport team will come and talk to you. They will explain your relative's condition. They may need to insert extra drips or tubes to make the transfer possible. They will tell you what will happen once the team arrives in Leicester. They will also ask you some questions about any past medical history. Any information you can think of is often very helpful to the doctors. They will also ask you to sign a consent form for the ECMO procedure.

### **I have already signed a form, why do I need to sign another one?**

The form you have already signed gave permission to include your relative in the research study. The next form is to give permission for the transport and the ECMO itself. This is standard procedure. It is really a way of making sure that the doctor explains everything to you as clearly as possible.

# ECMO Circuit



## The ECMO Circuit

The patient's blood travels out through the drainage tube (cannula) into the ECMO machine. In the oxygenators carbon dioxide is removed, oxygen is added and the blood is warmed to body temperature before being pumped back into the patient through the return tube (cannula). The ECMO circuit takes over the job of the lungs, giving the lungs a chance to recover.

### **What will happen to my relative at Glenfield Hospital?**

Your relative's condition will be re-assessed on arrival at Glenfield. If it has improved, the team may decide to treat without ECMO. This will mean a continuation of the type of treatment your relative is getting now. However it is most likely that ECMO treatment will be necessary. In order to start your relative on ECMO a small operation is required. This is done under a full anaesthetic. The doctors will insert tubes (cannulae) into the veins in the neck and the groin. These allow blood to be diverted into the ECMO machine where it will be oxygenated before being returned to your relative via the other tube. While on ECMO patients stay on gentle ventilation. The average length of time that patients stay on ECMO is around 8 days. However, many patients require longer courses of treatment, sometimes for several weeks.

### **Can I stay with my relative?**

Relatives are free to spend as much time at the bedside as they are able/wish to. However, so that the staff at Glenfield can provide you with information about your relative when you are not there, please give them a telephone contact number(s). We do not have specific visiting times. We can also offer you free accommodation at Glenfield while your relative is in hospital there. If you need help with arrangements to get to Glenfield please ask the nursing staff at this hospital. They will advise you after discussion with the ECMO Co-ordinator at Glenfield. If you need help with travelling and living expenses whilst at Glenfield the social worker can help you to claim these.

### **Are there any risks associated with ECMO?**

The main risk during ECMO treatment is bleeding. This is because a blood-thinning drug called heparin must be given to your relative. This is to prevent the blood clotting in the ECMO machine. In the early days of ECMO (in the 1970s) bleeding could be a serious problem. However, nowadays we have developed techniques that have almost eliminated bleeding in most patients. Nevertheless bleeding can still be a problem in some patients, especially if a surgical operation is required whilst on ECMO. It is possible that your relative could develop an infection while on ECMO. For this reason, we will check for signs of any infection on a daily basis and will give treatment to cure any infection, if it develops.

### **What are the advantages of ECMO?**

Briefly, the likely advantage of ECMO is that it can keep up the supply of oxygen while ‘resting’ the lungs. With conventional (non-ECMO) ventilator care, the ventilator is adjusted to make up for the patient’s reduced or absent lung function. This is done by increasing the amount of oxygen blown into the lungs by the ventilator and increasing the pressure at which it is delivered. This forces more oxygen into the blood. Unfortunately, we now know that high-pressure ventilation with large amounts of oxygen can actually cause further injury to the lungs and can prevent them from recovering. The main advantage of ECMO is that the pressure and oxygen concentration used to ventilate the lungs can be greatly reduced to safe levels. We call this gentle ventilation “lung rest”, and we believe that it may give the lungs a chance to heal and recover.

### **Can my relative choose not to continue with the study?**

As soon as your relative is discharged from the Intensive Care Unit and able to discuss the illness, the doctor will explain about this study. We will send written information to your relative when discharged home. Your relative may at any time choose not to stay in the study.

### **What would being in the study involve?**

The staff at the hospital and a researcher will collect information about the treatment that your relative has received while in hospital, from health service notes. Your relative and others closely involved may also be asked to complete short questionnaires. We also plan to follow up all patients in this study. This means that if your relative agrees to continue in the study, then we will inform his/her GP. A home visit will be arranged in about 6 months to assess your relative’s health and also to record events including personal costs related to your relative’s health. Of course, all information that we collect will be treated in the strictest confidence.

### **What if I have further questions?**

The doctor and nurse from the transport team will be happy to answer your questions. In addition, once you arrive at Glenfield any of the ECMO staff will be pleased to help and they will provide you with the usual relative’s information leaflet explaining about children visiting, and number of visitors at the bedside. We aim to keep you fully informed at all times.

### Further information at this hospital

Contact:

DOCTOR

TELEPHONE

NURSE

TELEPHONE

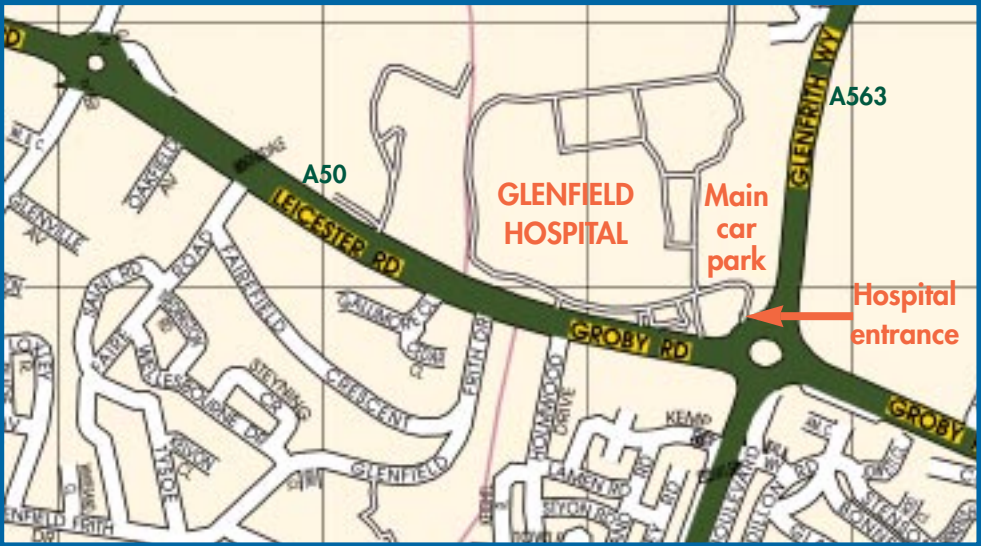
### Further information at Glenfield Hospital

ECMO Co-ordinator	0116 287 1471
Cardiac Intensive Care Unit (where your relative will be cared for)	0116 256 3159
Social Worker City Duty Social Work Team	0116 256 3605
Travel Expenses Claim (General Office)	0116 256 3400

**CESAR Data Co-ordinating Centre**  
**Medical Statistics Unit**  
**London School of Hygiene and Tropical Medicine**  
**Keppel Street**  
**London WC1E 7HT**  
**Tel: 020 7927 2376/2075**  
**Fax: 020 7637 2853**  
**Website: [www.cesar-trial.org](http://www.cesar-trial.org)**

# Directions to Glenfield Hospital

The main entrance to the hospital is in Groby Road on the roundabout where the A50 crosses the A563. Park in the main car park and then follow signs to the Cardiac Intensive Care Unit.



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