

Machine perfusion of donor livers: Normothermic perfusion and hypothermic oxygenated perfusion

Information for
patients



Thank you for taking the time to read this information leaflet. It is important that you read this, discuss it with relatives, friends and your GP if you wish, and ask us any questions you may have.

We would like to inform you about two new machines that have recently become available to our Transplant Unit for Liver Perfusion (normothermic or hypothermic) of donor livers. This leaflet will explain how these machines work and how they may affect what we do when a liver becomes available for you. It is important for you to understand why this new approach is being carried out and what it will involve.

Useful reference list:

NMP: Normothermic Machine Perfusion.

A method of keeping the donor liver at body temperature, while out of the body, by pumping blood through it.

HOPE: Hypothermic Oxygenated PERfusion

A method of preserving the donor liver cold, while out of the body, and providing it with oxygen at the same time.

Introduction

Liver transplantation is a highly successful form of treatment for many forms of end-stage liver disease. It is usual or common practice to keep the donor liver in ice, also known as cold storage, from the moment the liver is retrieved from the donor until the time it is implanted in the recipient. In recent years various alternatives to cold storage have been introduced in UK.

Normothermic Machine Perfusion (NMP): the liver is placed onto a machine, prior to transplantation, which keeps it at 37°C. Oxygenated blood, medications and other fluids are circulated through the liver. A number of tests can be done at this stage to test the quality of the liver and how well it will function once it has been implanted in the recipient.



A normothermic machine perfusion device (NMP) - OrganOx metra™

Hypothermic Oxygenated PERfusion (HOPE): the liver is placed onto a machine, prior to transplantation, that keeps it cold (4-10°C). A highly-oxygenated perfusion fluid is circulated through the liver for 1-2 hours whilst the operation for the transplant is prepared and started.



A hypothermic oxygenated perfusion device (HOPE) - VitaSmart™

What is the purpose of these new machines?

These machines have been designed to try to improve the function of the livers currently used for transplantation. They allow the clinical team to predict how well the liver will work once it has been transplanted in a patient. They may also reduce the risk of some complications that can occur after the transplant, such as damage to the bile ducts. Sometimes, in situations where we cannot carry out the transplant immediately, these machines may also be used to prolong the time that we can keep the liver viable after it has been retrieved from the donor to up to 24 hours.

Why have I received this information leaflet?

All the adult patients (aged older than 18 years) who are currently on the Liver Transplant Waiting List at St. James's University Hospital Leeds will receive this information. You may or may not be offered a liver that requires machine perfusion, this will be decided by the clinical team when the liver is retrieved. We will let you know, when we call you for the potential transplant if we are planning to use either NMP or HOPE for your donor liver.

You can at any time decide that you do not wish to receive a liver that has been preserved on either machine.

Do I have to accept a liver preserved on machine perfusion and what will happen if I choose not to?

No. You can decide whether to accept a liver preserved on machine perfusion or not. We will go through this information sheet in details with you and describe what will happen. This information sheet is yours to take away to consider further and discuss with others.

The National Institute for Health and care Excellence (NICE) has recently issued a guideline regarding machine perfusion of livers for transplantation. The guideline states that there are no major safety concerns and that machine perfusion can be used provided that:

- the clinical governance lead of the hospital have been informed
- the patients receiving such livers understand the procedure and possible risk and benefits

- the outcomes of patients receiving a liver preserved on machine perfusion are reviewed regularly.

We have informed the clinical governance lead and we will review the outcomes in our regular audit meetings, as we do for all liver transplants.

You can find more information on the NICE website:

<https://www.nice.org.uk/guidance/IPG636/InformationForPublic>

If you decide that you would like to take part you will be asked to sign an Informed Consent Form to confirm that you understand this information sheet. You will be given a copy of the signed Informed Consent Form to keep. If you do decide to take part, you are free to withdraw at any time and do not have to give a reason. If you decide not to take part, or to withdraw, this will not affect your medical care in any other way, or your relationship with the medical and nursing staff looking after you.

Please be reassured that, whether you decide to participate or not in this proposal, it will not affect your position on the waiting list and your chances of receiving a liver in the future.

What will happen to me if I take part?

If you are already on the waiting list for a liver transplant and you are happy to accept a liver preserved on machine perfusion, you will be asked to sign this consent form at your next clinic appointment or when you are called in for a transplant (if this happens before you're due to come back to clinic).

If you are being assessed for a transplant and deemed suitable to go on the waiting list, we will ask you to sign the consent form when you come for your listing appointment.

The use of these machines does not affect the way your surgery will be carried out.

All the information regarding the transplant that you have received at your listing appointment and that you can find in **book 1** are still valid.

When a donor liver is offered for you, the Transplant Coordinator will contact you by phone and inform you if we are planning to use either machine for the donor liver. You will be asked to verbally confirm that you are still willing to accept this. If you have any doubt or questions please let us know, as you may be woken from sleep when a liver becomes available, with little time to have your questions answered. The management and follow up after the transplant will be exactly the same as for routine transplant patients.

You do not need to undergo any extra investigations or procedures because of the way your liver has been preserved and every aspect of the management and follow up would be as standard of practice at present.

What will happen to me if I don't take part?

You will be on the same waiting list as the patients who decide to accept a liver preserved on machine perfusion. When a liver is offered for you, the liver would be deemed usable according to current standard criteria and it will be stored in an ice-box with a storage fluid as it is standard practice. There is no way of testing a liver's function using this method of preservation and there is a small risk that some livers do not function after transplantation as discussed as part of the consent process. Currently the majority of procedures are carried out this way.

What are the possible benefits of taking part?

Your decision to accept a liver preserved on machine perfusion will not affect your position on the waiting list, as most of the organs are offered via a national allocation system, and your decision will not influence this allocation policy.

The liver will be placed on either perfusion machine before your transplant; your transplant and the rest of your care will be as per standard practice of the unit.

- **NMP** is currently used in most transplant units in the country and experience suggests that, with this approach, we may be able to assess the risk of livers failing to work after transplantation. If there is any doubt about the ability of the liver to function whilst on the machine, it will not be used for transplantation. Experimental studies have suggested that the procedure may also improve the overall quality of the liver graft. Furthermore, livers that had been deemed too high risk to use, with the standard cold storage, have successfully been transplanted with this approach.
- **HOPE** is currently used in transplant units in UK and abroad. The studies available suggests that, with this approach, there may be a reduction in the risk of some complications that can affect the bile ducts, especially for patients who receive a liver from a donor who died from cardiac death (DCD).

What are the risks involved?

As you will be aware, liver transplantation is a major procedure that carries its own risks. The surgical and peri-operative risks are the same for any other liver transplant.

These machines have been shown to be safe to use as a form of organ preservation in the clinical transplant setting.

You are not exposed to a higher risk for transmission of HIV or hepatitis virus infections or any other infection as compared to other patients or liver recipients in general.

There is a small chance of technical failure of the machines that can lead to the liver not being usable for transplant. This can happen because the machine stops working, (power issues related to electrical supply or batteries) or because there is a problem with the tubes connected to the liver. These issues are rare but if any technical problem should become evident we will inform you immediately. If the technical problem is severe enough to render the liver not usable, we will not be able to proceed with the transplant.

The use of machine perfusion allows us to test the function of the liver before it is used for transplant. There have however been some cases of graft failure even after machine perfusion as can occur following the usual standard cold storage. The information currently available suggests that, using machine perfusion will not increase your risk compared to a “standard” liver transplant.

Will my data be kept confidential?

Your clinical data will be kept confidential, in line with the Trust guidelines, and shared only with clinical personnel directly involved in your care. Clinical data and blood samples taken from the donor liver, while on machine perfusion, may be stored for research purposes. If we plan to do so, we will give you all the relevant information and ask for your consent before your transplant.

It is important for you to know that any decision you will make regarding research does not affect your eligibility and access to transplantation.

We will share clinical information regarding your transplant with your general practitioner (GP), including information regarding the machine perfusion that we may have used for your donor liver.

What if there is a problem?

If you have a concern about any aspect of this proposal, you should contact a member of the transplant team. You can also withdraw your consent at any point without the need to give any reason.

Who can I contact?

If you have any questions or need more information, you should contact your hospital doctor or the Liver transplant coordinators at Leeds Teaching Hospitals NHS Trust on **0113 206 6509** (during working hours).

If you have a problem, concern or complaint, please ring Leeds Patient Advice and Liaison Service (PALS) on **0113 2067168** (during working hours) or **0113 206 6261** (during out of hours)

Email: patientexperience.leedsth@nhs.net

What if relevant new information becomes available?

Sometimes we get new information about the treatment being provided. If this happens, your doctor will tell you and discuss with you whether you should continue in the project. If you decide not to carry on, your doctor will make arrangements for your normal care to continue. If you decide

to continue in the project, he/she may ask you to sign an updated consent form. It is possible that your doctor might suggest you withdraw from the project. He/she will explain the reasons and arrange for your care to continue. If the project is stopped for any other reason, we will tell you and arrange your continuing care.



What did you think of your care?

Scan the QR code or visit bit.ly/nhsleedsfft

Your views matter



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