E-CLAD UK

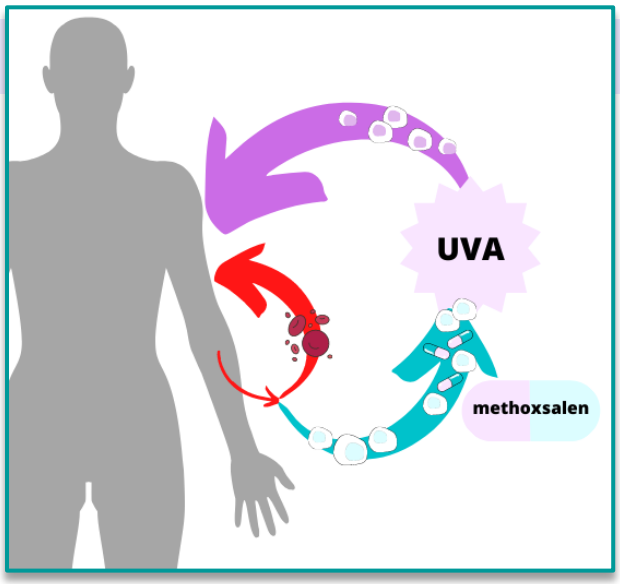
A research study to help improve treatment of chronic rejection after lung transplant

Chronic Lung Allograft Dysfunction (CLAD) is a complication that can happen after a lung transplant. CLAD develops when the immune system causes damage to the transplanted lungs, and lung function drops. It is also called chronic rejection.

E-CLAD UK is a research study that aims to find out if a therapy called **Extracorporeal Photopheresis (ECP)** treatment can be used to treat CLAD. The research is being done by a team of specialists from all 5 UK adult lung transplant centres.

ECP is currently used to treat various conditions involving the immune system. There have been a few small studies that suggest ECP could also help in the treatment of CLAD. However, there is currently not enough evidence for the NHS to say whether or not it should be used routinely to treat CLAD. The E-CLAD UK trial has been set up to answer this question.

This leaflet gives a short introduction to E-CLAD UK. Please ask your transplant team if you would like to find out more.



What is ECP?

ECP treatment involves passing a patient's blood through a machine that separates out the white blood cells. The red blood cells are returned to the body straight away.

The white blood cells are sensitised to light with a drug called methoxsalen, then exposed to UV (ultraviolet) light. This all happens inside the machine. The treated white blood cells are then returned to the body, where they trigger changes in the immune system.

This can help to stop the immune system from attacking the lungs, potentially slowing down or stopping the progression of CLAD.

What does the trial involve?

To find out if ECP can be used to treat CLAD, we need to compare its effects with the current usual treatment for CLAD that is available at the moment through the NHS.

The trial will involve 90 patients, who will all receive usual care for CLAD. On top of that, half of these patients will also receive a course of ECP treatment. When patients join the trial, they will be randomly allocated to one of these groups.

Standard care group → **45 patients will receive standard care (usual NHS treatment for CLAD) for 24 weeks**

ECP group → **45 patients will receive standard care (usual NHS treatment for CLAD) + a course of ECP therapy for 24 weeks**

9 cycles of ECP treatment: every 2 weeks for 12 weeks and then 4 weekly until week 20. Each cycle involves 2 treatments, lasting between 2-3 hours on consecutive days

Both groups will continue all their routine clinic appointments with their transplant team

Both groups will have monthly appointments with the research team to collect additional information and some additional blood samples

Both groups will be regularly monitored and treated appropriately throughout, including a **review after 12 weeks**. If the treatment you have been allocated doesn't seem to be working for you, you won't be stuck in the trial for 6 months– your doctor would explain other treatment options and you could leave the trial to access them at any point

Are there any benefits to taking part?

We can't promise that taking part in this trial would benefit you directly, although there is the possibility that the treatment you are allocated (either standard care or ECP) may help to treat your CLAD. We hope that the information we get from this trial will help improve treatment for patients with CLAD in the future.

Are there any risks to taking part?

There are always risks with undergoing any trial procedure and all medical treatments can lead to side effects. Your doctors and the research team will monitor your health regularly to ensure your wellbeing.

The main known side effect of ECP is that it will temporarily make you more sensitive to sunlight, meaning that you would have to take extra care of the sun for at least 24 hours after treatment. Other side effects can include tiredness, dizziness, feeling cold and a mildly raised temperature for a short time following treatment.

Would I need to travel?

For both groups, your monthly appointments with the research team would be coordinated with your usual clinic appointments whenever possible.

If you are in the ECP group, you would need to travel to your lung transplant centre (or their nearby ECP unit) for your treatment. Treatment is given on 2 consecutive days, and travel and accommodation costs (if required) would be covered for you and a carer.

Would taking part in the trial delay my treatment?

No, you would receive treatment as soon as it can be arranged. You wouldn't have to wait until all 90 patients have joined the trial – we will recruit on a rolling basis, so you would get started on treatment as soon as possible.

What would happen at the end of the trial?

Altogether, you would be in the trial for 24 weeks. After that, you would continue to be cared for by your usual clinical team. Please note that ECP treatment cannot be provided by the trial after your participation in the trial has ended. Access to ECP treatment outside of the trial might be possible but it would depend on local arrangements and funding. Please discuss whether this would be an option for you with your clinical transplant team.

How will my information be used?

In this research study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data in case we need to check it. We will make sure that no-one can work out who you are from the reports we write. The full information sheet tells you more about this.

Who can I speak to for more information?

Please speak to your transplant team who will be able to give you more details, including a full information sheet, and discuss the trial with you. Alternatively, scan this QR code with your smart phone or device for more information.