 

Patient information leaflet for treatment with Imlifidase to allow for kidney transplantation in highly sensitized patients

**Introduction**

You have been given this leaflet because you have antibodies in your blood that make finding a suitable kidney transplant very difficult. You are eligible for treatment with a drug called Imlifidase which has been licensed in Scotland to increase the chances of you getting a transplant.

**What is Imlifidase?**

Imlifidase is a drug given intravenously just prior to transplant that breaks down antibodies very rapidly allowing the transplant operation to go ahead. The medicine will break down both bad antibodies (those directed against the donor) as well as good antibodies (those that protect against infection). The medicine is given as a once only injection and cannot be given again at a later date. It is only licensed for use in deceased donor transplantation (waiting list), not live donor transplantation.

**Why am I eligible for Imlifidase?**

You have developed antibodies to other people due to exposure to their proteins. This occurs due to previous transplantation, blood transfusions or pregnancy and makes finding a suitable kidney difficult as well as increasing the risk of rejection after transplant. Imlifidase has been shown in trials to allow some patients who have these antibodies to be transplanted successfully. Imlifidase is only approved in the UK for patients with very high levels of these antibodies so only a very small number of patients in each unit will be eligible for this treatment.

**How does it increase my chances of getting a transplant?**

Currently your antibody levels mean that very few, if any, patients in the UK could conceivably be a donor for you. Imlifidase allows us to accept kidneys for patients even if a patient has antibodies against that donor. We will still avoid the highest risk donors, those to which you have the highest levels of antibodies against. Due to the priority patients with antibodies get on the UK kidney transplant waiting list, opening up even a small a window of opportunity in the number of potential donors will likely facilitate a transplant for many patients like you.

**What are the risks of this treatment?**

The antibody levels will drop very rapidly after receiving this drug and will stay low for some time but the levels do rebound back up, generally after a few weeks. To keep the kidney healthy and to prevent rejection, powerful immunosuppression treatment still needs to be given in patients who get this drug. Despite these powerful drugs, it is expected that many patients will still get rejection episodes which would need further treatment with immunosuppression medicines.

Due to the degree of immunosuppression treatment needed for patients who have antibodies to their donor, there will be an increased risk of infection after transplantation. Therefore, we need to ensure you are up to date with vaccinations and we will give you medicines to prevent infection in the months after transplantation.

**What vaccinations will I need?**

You will likely already have had some of the vaccinations you require. As per UK & Scottish guidelines, patients need to be vaccinated against pneumococcus (common cause of pneumonia), meningococcus (cause of meningitis), seasonal flu and Covid-19.

**What happen after transplantation?**

The transplant operation and recovery should be like any other patient. Your antibody levels will be monitored after transplant along with your usual blood tests. Your follow up appointments will be in your usual centre with input from the Edinburgh Transplant Centre doctors as needed. The likelihood of needing a biopsy of your transplant in the weeks and months following transplantation will be higher than a patient who does not have antibodies to their donor.

**What happens if I get rejection?**

Rejection is common after transplantation and does **not** mean that the kidney has failed. The risk of rejection is higher in patients with antibodies to their donor, even when Imlifidase is used, and these rejections may be more difficult to treat.

**What if I don’t want to get this treatment?**

That is perfectly fine, of course. It is your decision whether to accept this treatment or not. If you decide not to accept this treatment then you will remain on the waiting list for a transplant, although we know that the chances of finding a suitable kidney is low given your antibody levels. If a suitable kidney is found, it is still very likely you will need more powerful immunosuppression medicines as mentioned above and the risk of rejection will still likely be higher than usual, again due to the high antibody levels. You should discuss this treatment with your usual kidney doctors as well as the transplant team doctor you see in the transplant assessment clinic.

**Where can I find out more information?**

A link to the patient information sheet from the pharmaceutical company can be found here(https://www.medicines.org.uk/emc/files/pil.13155.pdf).