



## FOR YOUR INFORMATION

### Statins for Improving orGaN outcome in Transplantation The SIGNET study

**We are running a clinical trial involving organ donors, and you/ your child may receive an organ from one of these donors. We would like to tell you about this study which involves treatment of organ donors.**

#### **What is the study?**

The SIGNET study wants to find out whether giving a drug called Simvastatin to organ donors, will improve the outcome in the people receiving the organs after the transplant. This is a drug given to tens of millions of people around the world to lower their cholesterol level. But we think it may have specific and other advantages when given to organ donors.

#### **What is the background to the study?**

All donated organs have already suffered some damage; as the brain dies chemicals are released which cause inflammation. Measurements of this inflammation link to how well the organs will function in the person receiving the organ after the transplant. Drugs like Simvastatin reduce inflammation and we hope that giving Simvastatin to organ donors may improve how well the donor organs work in the people receiving the organs.

A study done in Finland, with only 80 donors, showed small advantages for those who received hearts, lungs and livers from donors treated with Simvastatin. The most important thing to note is that no group who received organs from treated donors did worse than those who received organs from untreated donors – they either did better or the same. This study established that giving the drug was very safe. We will be using the *same* drug in the *same* dose as in the study in Finland.

#### **Why are we conducting the study?**

Anything we can do, before the transplant, which may improve the transplanted organ could have a major benefit to patients receiving transplanted organs in the future.

#### **What does the study involve for organ donors?**

The SIGNET study will be recruiting 2,600 organ donors over 4 years. Organ donors will be randomly allocated to one of two groups in the study. One group will receive Simvastatin, the other will not. In every other way both groups will be treated the same.

#### **Why is this study relevant to me?**

As you/your child is currently on the transplant waiting list, you/ your child may in the future receive an organ from a donor who has been included in this study. Half of the people who receive an organ from a donor who has taken part in the study, will receive an organ from a donor given the drug.



As a possible recipient of an organ from a donor in the study, you need to be aware of the study but do not need to give consent as you/your child is not receiving the study medication which will have had its anti-inflammatory action in the donor. If you are already on statin therapy this will not affect the study or your treatment.

We believe no measurable quantity of Simvastatin will be carried in the organ being transplanted and therefore we do not think there are any risks to you/your child if you/your child receives an organ that has been treated with a statin. Simvastatin is a licensed, commonly used drug and we actually already know that many organ donors are already taking Simvastatin.

We will look at how well the organs are functioning after the transplant; comparing what happens in those who received the drug-treated organs, and those who did not. This is done with data already collected on people who have received an organ in the UK Transplant Registry. No extra data will be needed.

As of yet, there are no direct benefits to you/your child receiving an organ from someone taking part in the study. However, the evidence we collect from the study will help us to improve transplantation in the future.

### **What happens to my data?**

Following any transplant in the UK, the UK Transplant Registry records information about how well it is working and details of the recipient. Some of this is a legal requirement and some is to help audit the national transplant service. In this research study we will use some of the information gathered by the UK Transplant Registry from people who have received an organ from a donor taking part in the study. **We do not need to collect any extra information from you/your child or perform any extra tests.**

This UK Transplant Registry information will be linked to the research data collected from the organ donor participants. It will be undertaken by designated members of NHS Blood and Transplant (NHSBT) who are permitted to access the UK Transplant Registry. This will enable us to analyse the study information and help us understand how we might improve outcomes for organ recipients.

The information will be held securely in electronic format under the provisions of the Data Protection Act 2018 and the General Data Protection Regulation. People who do not need to know who you/ your child is will not be able to see any name's or contact details. Your/ your child's data will have a code number instead. You can find out more about the UK Transplant Registry at <https://www.odt.nhs.uk/information-for-patients/how-we-use-your-information/>.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you/your child received an organ from someone who took part in the study. The results of this study will be submitted for publication in scientific and/or medical journals, presented at scientific and/or medical

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conferences and made publicly available to inform transplant doctors in the UK and the rest of the world. You will not be identifiable in any publications.

**Who to contact for further information**

You are encouraged to ask any questions you wish. If you have any questions about the study, please contact the study team at [SIGNET@nhsbt.nhs.uk](mailto:SIGNET@nhsbt.nhs.uk) . If you require paper copies of any information please ask.