



**Plasma-Lyte Usage and assessment of kidney Transplant Outcomes in children**

We would like to ask you and your family if you want to take part in a research study. You have been asked because you are going to have a kidney transplant operation.

A research study is a way that doctors try and find out answers to questions to help people get better.

Before you decide if you would like to join, it is really important that you understand what the study is about, why it is being done and what it will involve for you.

Please read this leaflet and think about it carefully. Also talk to your family, doctor or nurse about it if you want.

If something doesn't make sense or you have more questions, then you can ask your parents/carers to give us a call and we can discuss it with you.

## Why are we doing this research?

This research study is being done to find out which fluid is best to give children after a kidney transplant operation.

After the operation, your doctors will have to give you a special type of fluid. The fluid contains lots of important substances such as salt (sodium).

Sometimes the extra fluid can make you feel poorly, causing headaches and making you feel sick. So, your doctors want to see whether a different fluid, called Plasma-Lyte, will work better than the fluid they normally use. Your doctors don't know the answer to this question yet, and the only way to find out is by doing this research study.

## Do I have to take part?

**No, it is up to you if you want to take part.** You can change your mind at any time.

## What will happen to me if I take part?

Before your operation, we will ask you and your parents/carers some questions, to make sure you still want to take part. If you are still happy to take part, you and your parents/carers will be asked to sign a form.



During and after your operation, your doctors will either give you the normal fluid, usually called saline, or the different

fluid, Plasma-Lyte. The decision of which fluid you will get is decided by chance, a bit like tossing a coin, but we use a computer to decide this instead. This means that half of the children taking part in this study will receive the normal fluid, and half the children will receive Plasma-Lyte. This is the fairest way to see which fluid works best.

The fluid is given through a thin plastic line (which all children have after a transplant operation).

Your doctors will check how you are feeling after your operation and record lots of measurements about how your new kidney is working. These measurements are always checked after a kidney transplant operation so you will not need to have any extra blood samples or tests.

We will use these measurements to decide which fluid helps to make the new kidney work better.

### **Will taking part help me?**

The study may not help you right now, but it will help doctors to know which fluid to use for children having kidney transplant operations in the future.

### **What if something goes wrong?**

If there is a problem, you can talk to your parents/carers and doctors at any time.

### **What if I don't want to take part anymore?**

Just tell your parents/carers and doctors carrying out the study that you don't want to take part any more. You don't have to give any reason. It is your choice.

### **What will happen at the end of the study?**

The results of the study will be written up so that people can read about it but they won't know you were in the study.

We will also contact you and your parents/carers to let you know what the results of the study are.

### **What if new information becomes available?**

Sometimes, in the time it takes to do a study, new information comes up. If this happens, your doctors will discuss with you and your parents/carers whether you want to continue in the study.

### **Will my information be kept private?**

All your information will be kept private. We will only inform people who have a need or right to know (like your parents/carers).

## Who is organising and funding this study?

There are special teams at NHS Blood and Transplant Clinical Trials Unit and Great Ormond Street helping to run this study. The lead doctor is called Dr Wesley Hayes and he works at Great Ormond Street Hospital.

## Who has reviewed and checked this study?

Before any research goes ahead, it is checked by a group of people called a Research Ethics Committee. They make sure it is fair.

Another group, called the Medicines for Healthcare Products Regulatory Agency also check that the fluids we are using are safe for use.

## What should I do if I have any questions?

Please ask your parents/carers first, then you can also speak to your doctor or nurse.

**Thank you for reading this!**

Visit [www.pluto-study.co.uk](http://www.pluto-study.co.uk) or scan me

