PLUTO

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

NHS
Great Ormond Street Hospital for Children
NHS Foundation Trust

Invitation to take part in this research

This hospital is taking part in a research study to investigate which fluid should be used during and after a kidney transplant operation. You are being given information about this research because you are going to have a kidney transplant and you are eligible to take part. Please take time to read the following information carefully and discuss it with your parents/carers and others, if you wish.

Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

Summary

This research study aims to find out which is the best fluid for children and young people receiving a kidney transplant. The standard fluid, most commonly saline, is given via a drip, both during and after the transplant operation in order to keep the new kidney working.

We want to investigate whether a different fluid, called Plasma-Lyte, is better than the standard fluid. In order to investigate this, we will compare changes in blood salt levels, symptoms and kidney transplant function (how well the new kidney is working) following your kidney transplant operation.

Please read the rest of this information sheet for further detail.

What is the purpose of this research?

Kidney transplantation transforms the lives of children and young people with severe kidney disease. It allows many to return to a life without very frequent hospital visits or dialysis treatment.

The transplant itself is a big operation, and in the first few days after kidney transplant, many children and young people develop abnormalities in the amount of salt and water in the blood. This is because doctors give very large volumes of artificial fluids into the veins to keep the new kidney working, and this dilutes the blood.

If the amount of the main salt in the blood (sodium) becomes too low, problems including fits and **very rarely** even death can occur. Because of this, blood samples are taken very regularly (every 2-6 hours) for the first day after the transplant operation to check sodium levels and take action to change them back to normal if necessary.

This research aims to compare the standard fluid used after the transplant operation with an alternative that may reduce abnormalities in salt (sodium) levels and help the transplant kidney to work better.

The fluid used as 'standard' actually varies throughout the UK. Doctors use a combination of different strengths of saline (water mixed with salt), and a fluid called Hartmann's (which also contains potassium and lactate). The alternative fluid is called Plasma-Lyte, which matches the normal composition of the blood more closely than the fluids which are being used currently. Although there are good reasons to believe that Plasma-Lyte may be a safer choice of fluid to use for a kidney transplant operation, there is not yet evidence which compares Plasma-Lyte with standard fluid for children and young people.

A total of 144 children and young people in the UK will be included in this study and this will allow us to compare the number in each group who have abnormal blood salt levels, and their transplant kidney function.

What is the alternative fluid?

Plasma-Lyte is not a new fluid. It is already approved for use in the UK and is given to other groups of patients, including children on intensive care and on children's medical and surgical wards.

Plasma-Lyte contains various substances such as sodium, chloride, potassium, magnesium, gluconate and acetate at similar levels to those in the blood.

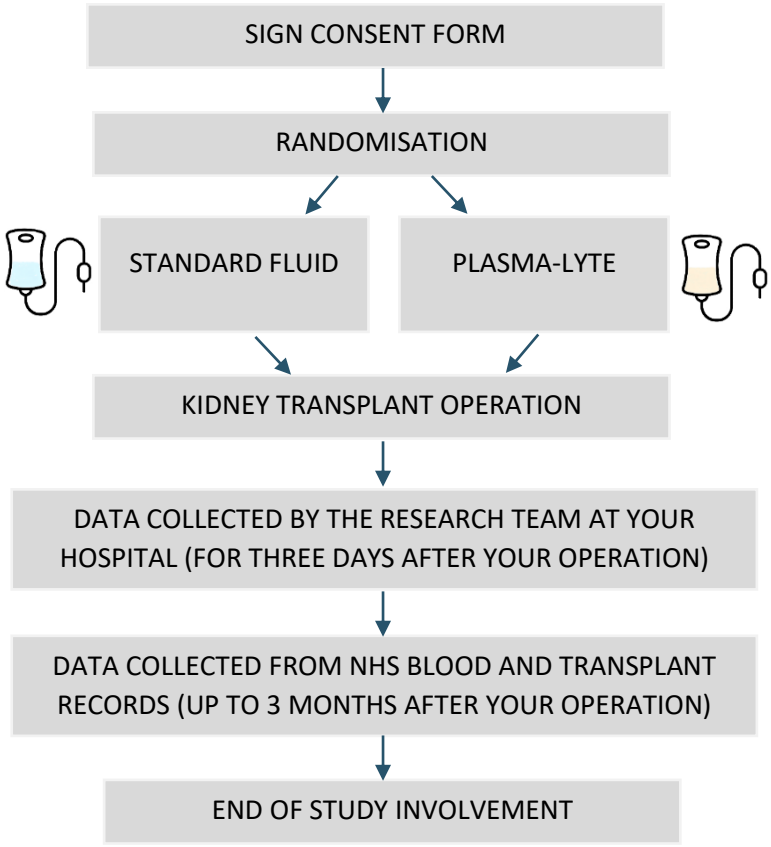
What will happen to me if I take part?

PLUTO is a 'randomised controlled' study. This will help doctors to work out which of the two fluids are best. The best way to compare the two options is to use each of them in two similar groups of patients. Everyone who agrees to take part in this study will be allocated to one of two groups. One group will receive the standard fluid and the other group will receive the Plasma-Lyte fluid. The only way to make sure that the groups of patients are as similar as possible is to have the treatment option decided upon by chance: a process called randomisation. Randomisation will be done using a computer on the day of the transplant operation. This process ensures that the two options are compared fully and fairly. There is an equal 50/50 chance of being in each of the two groups, and you will be told which group you have been randomised to.

Data will be collected about your transplant operation, blood test results and the function of the transplant kidney after the operation. You will also be assessed daily (for three days after the operation) for any symptoms of headache, nausea (sickness), pain and seizures. You will receive all the usual care that you would receive at this hospital. No extra blood samples, procedures or hospital visits will be required.

Your General Practitioner (GP) would also be informed that you are taking part in this study.

The diagram on the next page summarises what will happen if you decide to take part in the study:



As part of this research, we also want to explore your perceptions of the research processes to find out whether research studies like PLUTO are acceptable to patients. Once you've made your decision about whether or not to join the study, you will be given a short questionnaire. You don't have to fill this out – it is your choice. You may also be asked if you would agree to being interviewed by one of our researchers to discuss reasons for your decision. However, this is completely up to you.

What are the possible benefits and risks of taking part?

This research has the potential to improve the treatment and outcomes of children and young people receiving kidney transplants. Plasma-Lyte may reduce the risk of developing abnormalities in salt (sodium) levels after a transplant operation. Plasma-Lyte may also help the transplant kidney to work better, but at present we do not know if this will be the case. The PLUTO study will help to find out whether Plasma-Lyte is better than current standard care.

There are few risks to taking part in this study (above the risk of kidney transplantation). Abnormal levels of salts and minerals in the bloodstream can be experienced by children and young people receiving any fluid. We do not expect these to be more common with Plasma-Lyte but will monitor all children's blood levels closely to check for this.

Do I have to take part?

No, taking part in the research is entirely voluntary. It is up to you to decide. If you agree to take part, we will then ask you to sign a consent form. You will be given a copy of the information sheet and the signed consent form to keep. You are free to withdraw participation in the research at any time, without giving a reason. **This will not affect the standard of care you receive in any way.** If you turn 18 before you receive your kidney transplant, you will no longer be eligible to participate in this study.

What if new information becomes available?

Sometimes during a study, new information becomes available about the treatment that is being studied. If this happens, the Research Team will tell you about it and make sure you are happy to continue in the study.

How will we use information about you?

We will need to use information from your medical records for this study, including your blood test results. This information will include your initials, age and study ID number. Blood test results will be fully anonymised (using the study ID number only) and will be sent securely to the Digital Research Environment Team, based at Great Ormond Street Hospital. With your permission, we will also use some of the data which is already provided to NHS Blood and Transplant (NHSBT). To do this, we will use your unique recipient number, which is allocated by NHSBT when you were registered for a kidney transplant. People will use this information to do the research or to check and make sure that the research is being done properly.

We will keep all information about you safe and secure. 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 took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason. We will keep the information that we already have, unless you prefer us not to.
- If you choose to stop taking part in the study, we would like to continue collecting information about your transplant from NHSBT records. If you do not want this to happen, let us know and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- At www.hra.nhs.uk/information-about-patients
- Our leaflet available from www.hra.nhs.uk/patientdataandresearch
- By asking one of the Research Team
- By sending an email to the Data Protection Officer at Great Ormond Street Hospital (your.data@gosh.nhs.uk)

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can contact the Information Commissioner's Office (ICO).

Who is organising and funding this study?

The PLUTO study is being co-ordinated by the NHS Blood and Transplant Clinical Trials Unit and is sponsored by Great Ormond Street Hospital NHS Foundation Trust. The Chief Investigator is Dr Wesley Hayes at Great Ormond Street Hospital. The study is supported by the British Association for Paediatric Nephrology and the Children's Specialty of the UK Clinical Research Network. The study is being funded by National Institute for Health Research, Research for Patient Benefit Programme (NIHR RfPB). The research has been reviewed and approved by all these organisations. You or your doctor will not be paid for taking part in this study.

What if something goes wrong?

In the unlikely event that something does go wrong and you are harmed during the research due to someone's negligence then you may have grounds for a legal action for compensation against the NHS Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This is to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the London Central Research Ethics Committee. It has also been authorised by the regulatory body in the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) and your hospital's Research and Development Office. It has also been reviewed by patient and parent/carer representatives.

Where can I go for more information?

If at any time during the study you have questions or concerns, you can contact the local Principal Investigator or Research Nurse:

Principal Investigator
[details]

Research Nurse
[details]

You can also visit the PLUTO website at www.pluto-study.co.uk. Alternatively, you can visit or contact your local Patient Advice and Liaison Service (PALS) for independent advice:

[address]
Tel: [phone]

Thank you very much for taking the time to consider participation in the PLUTO study.

Visit www.pluto-study.co.uk or scan me