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Platelet function in critical illness and liver disease
Consultee Information Sheet

We would like to invite your relative, friend, or person you are representing to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for them. This study is being conducted as part of Miss Tyler Horn's Doctoral degree at the University of Reading. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of this study?

Platelets are a type of blood cells important for blood clotting. In health, this is the process that stops cuts from bleeding. However, in liver disease, this process can become dysregulated. We are studying how critical illness and liver disease affect the factors that control the function of platelets. We hope this research will enable us to improve care for seriously ill patients in the future.

Who is taking part in this study?

We are recruiting adult patients who are ill enough to have needed admission to Intensive Care, and who have either existing liver disease or evidence of liver dysfunction as a result of their critical illness.

Why are you being asked about this study?

As a result of their medical condition or treatment your friend, relative or person you are representing has become too unwell to consent to us enrolling them into the study themselves. This is known as 'loss of capacity to consent' and we are approaching you as their 'consultee' to ask if you would be prepared to discuss whether they might agree to take part in our study.

What is a consultee?

A personal consultee is normally a friend or a relative who knows the patient and who is able to advise us about their wishes and feelings and whether they might agree to take part in the research. When your friend, relative or person you are representing is well enough again, we will ask them to confirm the decision made while they were unable to agree themselves.

Do you have to agree?

No. It is up to you to think about the wishes of your friend, relative, or person you are representing. We will explain the study and go through this information sheet with you. If you do decide to continue, you will be given this sheet to keep and will be asked to sign a declaration form. The patient is still free to withdraw at any time, without giving a reason. This will not affect the care they receive.

What will happen to the patient if they take part?

If you decide the patient you are representing would be likely to agree to take part, we will take a small number of extra blood samples. We will then study their platelets in our laboratory using state-of-the-art techniques. We will look at how the function of their platelets changes over time in the ICU, and possibly afterwards when they are recovering on a ward.

The study will be purely observational. This means taking part will not change the medical treatment that they receive from the doctors and nurses responsible for their care in any way. We would take samples a maximum of five times whilst on ICU. Patients in ICU have lines in already to allow regular blood samples without using a needle, so taking part will not mean any additional discomfort while they are in ICU.

We will also take blood samples up to twice when the patient moves to a ward after discharge from ICU, but we will ask their permission to do this. If the patient comes to an outpatient clinic for follow up in the next few months, we might also ask their permission for a final blood sample at that time.

What will happen to any samples the patient gives?

Blood samples they provide will be analysed in the Platelet Function Group laboratory at the University of Reading. We will look at how their platelets work, what proteins they produce, and how they interact with other substances in the blood involved in clotting. We will not store any of their blood cells once these

tests are finished but we may freeze platelet protein extracts, blood plasma, and serum for later analysis. Storage would be for up to 5 years after the end of the study, after which time any samples remaining will be destroyed.

Are there any disadvantages or side effects of taking part?

This study is simply designed to study the function of patients' blood cells rather than alter the care they receive in any way. It is highly unlikely that a patient would suffer any harm by taking part. Taking part means having extra blood samples taken, but the volume of blood taken each time is very small compared with that taken routinely each day for an ICU patient - no more than 50 ml (less than three tablespoons).

What are the possible benefits of taking part?

This study will not be of immediate benefit to those who participate, but it may help us to improve the standard of care for patients in the future who are admitted to ICU. We hope that the information we collect will ultimately allow us to understand better the effect of critical illness on platelets, eventually improve patient care in the future, and ultimately save lives.

Are patient details kept confidential?

All information collected during the study will be kept strictly confidential. The information collected on study patients is kept in a secure area of the hospital. All computer systems are on secure networks. Only the research team will have access to the stored information. Responsible members of the Royal Berkshire NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure we are complying with regulations.

Any data that leave the hospital will be anonymised; all names and addresses will be removed, and it will not be possible to identify individuals from the information. Patients will not be identified in any published article about this study.

What will happen to the information if the patient decides later that they no longer want to take part?

If you decide that the patient you are representing would be likely to agree to take part in this study but when we discuss this with them in the future they do not agree to the use of the information we have collected, their information will be destroyed.

Is there a contact point where you can seek independent advice about patients' participation in this study and your role as a consultee?

Yes. The National Institute for Health and Care Research has information about taking part in research studies: www.nihr.ac.uk/patients-carers-and-the-public

Specific information about research in ICU in patients lacking capacity to consent can be found here: https://bepartofresearch.nihr.ac.uk/taking-part/Consent

Is there a payment for being in this study?

There is no payment for taking part in this study.

What if there is a problem?

In the case of a patient suffering harm, NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Dr Matthew Frise on 0118 322 8840 or email matthew.frise@royalberkshire.nhs.uk .

If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to any of the researchers, you can contact the Royal Berkshire Hospital Patient Advice and Liaison Service (PALS) on 0118 322 8338 or email PALS@royalberkshire.nhs.uk .

Who is organising and funding the study?

The study is being conducted by researchers from the Platelet Function Group at the University of Reading and intensive care doctors at the Royal Berkshire Hospital. The teams have many years of experience in successfully carrying out research in these areas. The study is funded by the Royal Berkshire NHS Foundation Trust and the University of Reading Health Innovation Partnership.

Who has reviewed the study?

All research is assessed by an independent group of people, called a Research Ethics Committee to protect patients' safety, rights, wellbeing and dignity. This research was approved by the South Central - Oxford C Research Ethics Committee.

Where can you find the results of the study?

If you would like a summary of the results, please indicate this on the declaration form you sign and we will send them to you once the study is complete. We will also offer this option to the patient when we ask for consent to use their information.

Thank you for taking the time to read this information leaflet. Once you have had time to consider this study and have had any questions answered, please sign the declaration form if you think the patient would agree to take part.