Application of Point of Care Testing (POCT) Full Blood Count (FBC) analyser in neonatal (<2 months) clinical care

Information sheet for guardians of participant

A Full Blood Count (FBC) is a routine blood test that is commonly performed on neonates (new born babies) as part of their clinical care. This blood can sometimes become clotted during the transport of the blood to the laboratory (where the sample is tested) and is no longer suitable for testing. Samples that are reported as "clotted" required the clinical team to collect another blood sample from the baby (*reported as between 20-30% samples affected*). This has a negative effect on the baby's care in the following ways:

- More blood is needed to be collected from the baby
- The baby will require an additional heal stab for the sample collection
- There is a delay in the reporting of the FBC results

The pathology team at Harrogate hospital (sponsor) have the opportunity to trial a new device which is placed on the ward and will analyse these samples for FBC. The analyser is called a Point of care testing (POCT) analyser as it is it placed at the point where the baby's medical care is delivered and not in the laboratory; no transport of the sample is required.

WHAT IS THE PURPOSE OF THIS STUDY?

This study aims to gather data to determine whether this analyser could potentially be used in the routine care of neonates (<2 months age).

The new analyser can offer faster results; require smaller, less invasive blood samples and the test can be performed on the neonatal ward, close to where the clinical care is being delivered. It is hoped that this will reduce the number of clotted samples that are reported and prevent repeat blood samples from being collected.

The new analyser is not currently approved for clinical use in neonates < 2 months of age. This is an early study which will assess whether this analyser is suitable for further evaluations to be carried out to enable it to be placed in routine service. If placed in routine service use this will help the clinical team to overcome the problems with clotted samples that have been outlined above.

Picture of the new analyser

Picture of the blood sample

WHY HAS MY CHILD BEEN CHOSEN?

We have invited all neonates (male and female) under 2 months of age to volunteer to take part in this study at Harrogate Hospital so we can gather data to ensure this device is safe to use in routine clinical care. Guardians of the child are those who can give consent for participation in this trial.

WHAT WOULD TAKING PART INVOLVE?

The clinical team will only request and collect samples that are required for the care of your child. We will not be collecting any additional samples and we will only be analysing those samples, already collected, for FBC. The results of the additional FBC will be reported in the research trial and anonymised; they will not be acted upon clinically or reported in your child's medical record.

When a FBC result is required for the clinical care of your child:

The blood sample will be collected in a blood tube; then 1-2 small drops of blood from the lid of the blood tube will be added to the sample collection device. This is then loaded into the new analyser. The remainder of the sample will be sent to the laboratory for analysis and clinical decision-making.

The results from the new analyser will be compared with the laboratory and a statistical analysis will be completed to determine whether the new analyser is suitable for use in neonates.

We will only use blood on a maximum of two occasions from your child during their hospital stay.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF MY CHILD TAKING PART?

There are no known risks that we are aware of.

The sample that is required is extremely small. We will be using 1-2 drops of blood from the blood that has already been collected for a FBC. This will be collected from the lid of the tube.

This is a unique opportunity to develop a method for use in neonatal medicine. It would reduce the number of blood samples rejected due to clots, reduce the time taken

for the clinical team to obtain a FBC and reduce the amount of blood needed for this test.

DO I HAVE TO TAKE PART?

No, Taking part is not compulsory. This is an invitation to join the study and guardians of the infant have every right to refuse consent for their child's blood to tested in this way.

If you wish to be informed of the outcome of the study please advise us and add your contact details on the consent form.

HOW WILL WE USE INFORMATION ABOUT YOU?

Data protection

We will only use information about your child that we need for the research study. The information required is your child's name, Hospital number and date of birth. Only two members of the core investigation team will have access to the full data including your child's name. Your child's data will be coded number in order to anonymise all information about the child, keeping it safe and secure. Everyone involved in this study will then use that code. We will also follow all GDPR privacy rules.

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. We will make sure no-one can work out who you are from the reports we write.

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, but we will keep information about your child that we already have. If you do not want this to happen, tell us and we will not include this. This will not affect the standard of care that your child receives.

Amy Howard is the lead nurse on the ward for this study, please contact any nurse on the ward if you wish to withdraw your child from this study and Amy will oversee this.

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 [Harrogate R&D website]

• by contacting HDFT Data Protection Officer (Jo Higgins jo.higgins@nhs.net or 01423 555697).

• by sending an email to nicky.hollowood@nhs.net or n.jassam@nhs.net

• by ringing us on 01423 55 3055

WHO HAS REVIEWED AND APPROVED THIS STUDY?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favorable opinion by Edgbaston Research Ethics Committee (REC).

This study has been discussed with Patient and Public Improvement and Engagement Group (PPIE) and their recommendations contributing to this final document.

WHO SHOULD I APPROACH IF I AM UNHAPPY WITH THE STUDY?

If you have any concerns about the study and your involvement in it or you would like to make a complaint, you may directly contact the Research and Development Department (R&D) in Harrogate Hospital.

Contact details are:

Michelle Platton; michelle.platton2@nhs.net

Research and Development Department

Harrogate and District NHS Foundation Trust (HDFT)

HG2 7SX

01423 555692

The patient experience team are an independent resource that are available to contact:

hdft.patientexperience@nhs.net

INDEMNITY

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against [Harrogate and District NHS Foundation 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).

GENERAL INFORMATION:

There are a number of web resources, such as the NHR website, available which provide further information in respect of serology testing and measurement. For further information about this research study, you may also contact:

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