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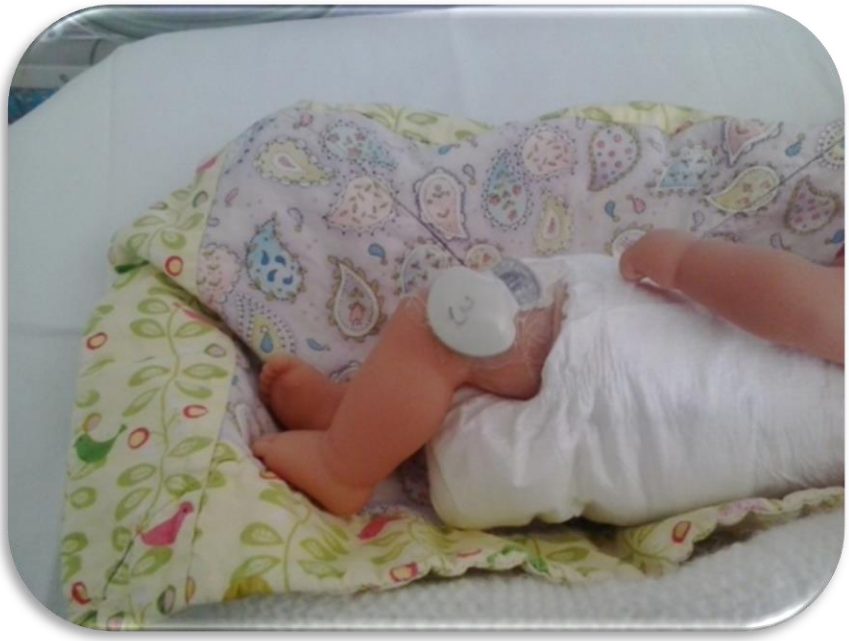
The REACT Study



Information Sheet for Parents

Real Time Continuous Glucose Monitoring in Neonatal Intensive Care (REACT)

We would like to invite you and your baby to take part in our research study. Before deciding whether your baby takes part you need to understand why this research is being done and what it involves. Please take time to read the following information carefully and talk to others about the study if you wish. Please ask us if anything is not clear or if you would like more information.

Section 1 tells you the purpose of the study and what will happen if you decide that your baby can take part.

Section 2 gives you more detailed information about the conduct of the study.

Section 1: Purpose of the study and what will happen

1.1 What is the purpose of the study?

We want to see if we can improve the way in which we control blood sugar levels in babies born very early. We want to see if a device that can continuously monitor sugar levels can help us to manage their sugar control. The monitoring device is currently used in children and adults with diabetes who also have high and low blood sugars.

1.2 Who is being invited to take part?

Babies can join the study if they weigh less than 1200g at birth and are less than 24 hours old. These are the babies most at risk of having high blood sugar levels. We plan to include 200 babies from selected Neonatal Intensive Care Units in the UK and Europe.

1.3 Does my baby have to take part?

Taking part in this study is completely voluntary. If you agree for your baby to take part you will be asked to sign a consent form. However, you are free to change your mind and leave the study at any time without giving a reason. If you choose for your baby not to take part or you want your baby to leave the study, your baby's future medical treatment and care will not be affected in any way.

1.4 What will happen to babies who take part in the study?

There are two study groups (study arms). There is an Intervention arm and a Control arm. Babies taking part in the study will be divided equally between these study arms in a random way (by chance)

much like flipping a coin. Neither you nor the doctors will be able to choose which arm your baby joins.

All babies will have a fine sensor placed under the skin on their thigh which can stay in place for up to a week. This sensor connects to a continuous sugar monitor which will record sugar levels. In both study arms a continuous recording of the blood sugar will be made that can be studied later. The difference between the study arms is that the continuous measurements in the intervention arm can be seen by the nurses and doctors as they are recorded.

Intervention Arm – The continuous sugar measurements of the babies in the intervention arm will be displayed on a small screen at the cot side. This information will be used to guide clinical management. Nurses and doctors will give glucose and insulin using a specially designed guideline that aims to reduce the number of high and low sugars.

Sugar levels displayed continuously on monitor

Control Arm – The same monitor will be used to measure sugar levels continuously but the screen will be covered so the readings cannot be seen. The babies will have their sugar control managed according to standard clinical practice with blood testing for sugar levels. Treatment for high and low sugar levels will be guided by usual clinical practice.

At the end of the study the stored continuous sugar levels will be compared with those of the babies in the intervention arm.

After the sensor is removed on Day 7 we will ask you to fill in a simple questionnaire to tell us how you felt about the study.

1.5 The Devices and Procedures

These devices are used routinely in children with type 1 diabetes. In this study we will be using the devices 'off label' as the licence is for people with diabetes and preterm babies who do not have a diagnosis of diabetes. However a small study has been undertaken in Cambridge using a similar device. Similar sensors have been used in over 400 preterm babies without complications. The continuous glucose monitors and sensors will be supplied by Medtronic Limited.

Continuous glucose monitoring will last for up to 6 days. We will also collect information for the study until your baby has reached 36 weeks corrected gestation. This means until the time your baby would have reached 36 weeks in the womb.

Table 1: Study schedule

Study Days	What is involved
Day 1	▪ Discussion with you about the study and whether you are happy for your baby to take part ▪ We will ask you to sign a consent form ▪ Information about your baby will be collected from the medical notes ▪ Weight, length and head circumference will be measured and recorded ▪ Randomisation to Intervention or Control study arm ▪ Sensor inserted in thigh
Day 1 – Day 6	▪ Sugar monitoring and management according to study arm
Day 7	▪ The sensor will be removed ▪ Clinical information about your baby will be recorded ▪ Weight, length and head circumference will be measured and recorded ▪ Parents will complete a questionnaire
Day 14	▪ Clinical information about your baby will be recorded ▪ Weight, length and head circumference will be measured and recorded
36 weeks gestational age	▪ Clinical information about your baby will be recorded ▪ Weight, length and head circumference will be measured and recorded

1.6 Expenses and payments

We cannot offer you any payment for allowing your baby to take part in this study.

1.7 What will I have to do?

Before deciding if you would like your baby to join the study you will have the opportunity to further discuss the study with the research team. Please ask any questions you may want to be answered. If you feel that you need more time to consider your decision please let the research team know. If you would like your baby to join the study you will be asked to sign the consent form. You will be given a copy of your signed consent form to take away and refer to later.

This will include your consent to keep your contact details in case we need to contact you in the future. We may invite you to provide more information about your baby's health and development or join new studies.

We will ask parents of babies in the intervention arm to complete a questionnaire about their experiences of having their baby's glucose control monitored by a continuous glucose monitor.

1.8 What are the possible disadvantages and risks of my baby taking part?

Your baby may feel slight discomfort when the sensor is inserted and there is a small risk of mild bruising at the sensor site. The sensor does not cause any discomfort once inserted. Infection is also a possibility but has not been reported in any of the 400 babies previously studied. It is possible that when high sugar levels are being treated that the level will get too low. However, it is hoped that continuous sugar monitoring will tell the staff how quickly the level is changing and prevent this happening.

If your baby goes home or is discharged to another hospital before 36 weeks gestational age the study team may need to contact you to ask about your baby's progress.

1.9 What are the possible benefits of my baby taking part?

We cannot say that your baby will directly benefit from taking part in this study. However, the information collected may inform doctors in the future about how best to manage sugar control in preterm babies. Many parents find involvement in research studies, which aim to improve clinical care of future preterm babies, a positive experience. During your stay in the Neonatal Intensive Care Unit, the study team also aim to be an additional resource for information and support.

1.10 What happens when the study stops?

After the study your baby will continue to be treated according to local guidelines and policies.

1.11 What if there is a problem?

If you have any concerns about any aspect of this study, please speak directly to the study doctors who will do their best to answer your questions.

1.12 Will my baby's taking part in this study be kept confidential?

Yes. We will follow ethical and legal practice and all information about your baby will be handled in confidence. Details are included in section 2.

Section 2

2.1 What will happen if I don't want my baby to carry on with the study?

You are free to stop your baby from taking part in this study at any time without giving a reason and without affecting your baby's treatment. Any information, including results from tests already performed will be used in the study unless you ask for these data to be destroyed.

The study doctor or Consultant in charge of your baby's care may also choose to withdraw your baby from the study if they feel it is in your baby's best interests.

2.2 What if there is a problem?

If you have any concerns about any aspect of this study you should speak to the research doctor who will do their best to answer your questions. The Patient Advice and Liaison Service (PALS) at your hospital are available to provide further advice and support.

If you wish to make a formal complaint about any aspect of the way you/your family have been approached or treated during this study, the normal hospital complaints procedure will be available to you. The NHS and the University have indemnity and insurance cover in place for all aspects of the study. This covers negligent acts or omissions and provides compensation in situations where blame is difficult to apportion, that is, even if it is difficult to determine who is at fault.

2.3 Will my baby's taking part in this study be kept confidential?

All information collected about your baby as a result of taking part in the study will be kept strictly confidential. All personal and medical information will be kept in a secured file and be treated in the strictest confidence. You may ask to see your baby's personal information at any time and correct any errors if necessary.

Once you have agreed that your baby can take part in this study they will be allocated a unique study number which will be used on all study documentation. This number will be linked to their personal information and your baby will only be identified by this unique number.

We will inform your baby's Clinical team that you are taking part in this study.

Authorised staff, who work for or with the Sponsor of the study, the hospital Research & Development Department or the Regulatory Agency responsible for medical device research may require access to your baby's personal information and/or medical records to verify the data for this study and ensure

that it is being conducted in accordance with UK law. All information will be treated in the strictest confidence during the review process.

2.4 What will happen to the results of the study?

The results of the study will be anonymous and your baby will not be able to be identified from any of the data produced. When the results of this study are available they may be published in peer-reviewed medical journals and used for medical presentations and conferences. If you would like to obtain a copy of the published results please contact your study doctor directly who will be able to arrange this for you.

Newsletters will be sent to you during the study to inform you how the study is progressing and at the end of the study when the results become available.

2.5 Who is organising (sponsoring) and funding the study?

This study is sponsored by Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge and is funded by the National Institute for Health Research.

2.6 Who has reviewed this study?

All research within the NHS is reviewed by an independent group of people called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by National Research Ethics Service Committee East of England – Cambridge Central.

Thank you for taking the time to read this information sheet.

If you require further information or have any questions please contact:

Principal Investigator

Name, address and contact details

Study Nurse: name and contact details

Complaints manager name and contact details

The REACT study is supported by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR partnership.