



# **BiHiVE 2 study**

## **The Investigation and Validation of Predictive Biomarkers in Hypoxic-ischaemic Encephalopathy**

### **Information Leaflet for Parents**

#### **What is the BiHiVE study?**

Some baby's require resuscitation when they don't cry or move after delivery. This may occur when a baby has had a difficult or stressful time during labour, or before delivery. Sometimes this can even lead to long term injury to the baby. The injury which we worry about the most is newborn brain injury. This type of brain injury is called hypoxic-ischaemic encephalopathy or HIE. As your baby has required resuscitation they may need careful monitoring for the next few days. We have no good way of knowing whether your baby has had a significant injury, and usually can't tell for sure until at least 24 hours after birth. The BiHiVE study hopes to find chemical and protein markers

in the blood which can tell us very soon after birth which babies have suffered significant injury so that we can intervene and improve their outcome. At the moment we have no good reliable early marker which can give us this information straight after birth. We hope that in the future a simple blood test at delivery will be able to give doctors and parents more information within hours of a baby's birth.

Because your baby has needed resuscitation at birth, blood has been drawn from the umbilical cord and placenta after the baby was born. This is the standard care in our hospital and many other modern maternity hospitals. This blood is used to measure acid levels in the blood. We have also drawn extra blood and stored it in 3-4 tubes. If you wish your baby to take part in the study we will store this blood to use for research into newborn brain injury. If you do not wish to take part in the study these samples will be destroyed.

If your baby is admitted to Neonatal Intensive Care Unit, and, if they are having a blood test as part of their routine care, we will ask for an extra 1.5 milliliters of blood on the first, second and third day of life. We will not disturb your baby an extra time for this sample, and if your baby does not require a blood test for other reasons, we will not take this sample. These samples will be frozen and stored for analysis.

Our current best way of looking at those who might be at risk of brain injury is to carry out a recording of their brain waves using an EEG machine. This is routinely done on the neonatal unit. We want to be able to compare what is currently our best method, to the simpler blood test which we hope to develop, and therefore all babies in the study will also have an EEG if they have signs of brain irritation (HIE).

In order to help babies who have difficulties after birth, it is also important for us to study babies who have had normal, uneventful deliveries. These babies act as controls so that we can know that the changes we find in the unwell babies are genuine. If your baby is a control infant, blood is taken from the umbilical cord and stored at birth. We will follow up your baby with an examination the day after birth. This takes about 5 minutes and will not upset your baby in any way. It can be carried out when they are still asleep in many cases. In addition we would like to contact you at 2 years of age to look at the growth and development of your child. The researchers will be very clear with you to reassure you that your baby is a control, or well baby.

### What will the study involve?

If you are happy for the research team to follow your baby after they are born, the extra samples of blood taken from your baby's umbilical cord will be frozen, stored and analyzed later when we have collected enough samples. An additional 1.5 milliliters of

blood will be taken if the baby is having other blood samples on day 1, 2 and 3, these will be analyzed once enough samples are collected. We will look at many different chemicals and proteins which may change in babies with significant brain injury. We will compare the levels to those of babies who did not need resuscitation. Your baby's progress after birth will be recorded. If your baby needs any extra medical care the details of this care will be collected from your baby's medical notes. This information will be anonymous, and will be identified only using a study number, not your baby's name or address.

We will also ask you to meet us again at 24 months of age so that we can record the progress and development of your baby. You will be contacted and an appointment will be made for a follow up assessment at a time convenient for you and your family. This will happen in the Cork University Hospital. In these follow up appointments, your baby's development will be assessed and discussed with you. Your baby will not need any further samples to be taken after the initial sample from the placenta for this study.

### What are my options?

Being part of the BiHiVE study is completely voluntary. You or your child can withdraw from this study at any stage. Not being part of this study will not affect any part of the medical care of you or your baby.

The BiHiVE study will be managed by the staff of the Department of Paediatrics and Child Health, University College Cork. We will publish our results in international medical journals. Once a year we will organize a meeting to tell families about how the study is progressing.

### Where can I get more information?

If you have any questions regarding the BiHiVE study, please contact the research coordinators

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