



Genomic Imaging in Neonatal Encephalopathy (GENIE STUDY)

Parent Information Leaflet

We understand that you may be feeling anxious with your baby's admission to the neonatal unit. Nonetheless, we think it's important for you to be informed about research opportunities for you and your baby.

Why am I being contacted to participate in this study?

All babies with neonatal encephalopathy (brain injury associated with birth asphyxia) are eligible to participate in this study. We understand that your baby has been admitted to the neonatal unit with a possible diagnosis of neonatal encephalopathy.

Why do we need this study?

Neonatal encephalopathy is a condition related to a lack of oxygen and blood flow to a baby's brain around the time of birth. We routinely offer cooling therapy to these babies in NHS hospitals. However, they may still have long term developmental problems, despite cooling therapy.

Recent evidence suggests that subtle genetic variations can influence how babies respond to this type of brain injury. Therefore, we need to understand the genetic variations so that in the future we can develop personalised medicines to treat babies more effectively.

What is involved in taking part in this study?

Your baby will have a number of blood investigations as part of their standard care at the time of admission to the neonatal unit. A small part (half a teaspoon, ~3ml) of these samples will be collected for research purposes. In most cases, the neonatal nurses or doctors may have already collected this blood sample. If you decide to take part in the study, we will use this blood sample to perform the gene testing.

It is important that you take sufficient time to consider this study, and you can ask us any questions before deciding whether you want to take part. Participation is voluntary and you are free to change your mind about the study at any time, without affecting the quality of care your baby receives.

If you wish to participate, you will be asked to sign an informed consent form (we will give you a copy). If you agree, we will also collect 5ml of blood from you and your partner (biological parents) to examine if you have similar genetic variations. If you do not wish to participate, we will discard the blood samples obtained so far and no more research samples will be collected.

What other information will you collect?

As part of our routine clinical care, your baby will have a brain scan (MRI) within few weeks after birth to assess brain injury and then a detailed neurodevelopmental examination at two years of age. We will collect the information from both of these exams to compare with the gene testing results. Where sufficient quality MRI scanners (i.e. '3 Tesla') are not available, the scan will be arranged at another local hospital.

What gene testing are you doing?

In the first part of the study we will examine how often genetic variations occur and how this influences the baby's response to brain injury. In the second part of the study, we will compare this with their MRI scans at birth and their performance in developmental tests at two years of age. We will also compare the genetic variations between parents and their babies.

Some of this testing will be done in the UK, and some in other world leading research laboratories in the US and Europe. We will remove all identifiable personal information from the collected blood samples, instead giving them a unique code for secure transportation.



Who has reviewed and approved this study?

This study has been approved by the UK Health Research Authority and the South West – Exeter Research Ethics Committee. The study is funded partly by a doctoral fellowship by the Medical Research Council, and partly by an endowment chair grant from the Weston Garfield foundation to Dr Thayyil.

What are the possible risks and benefits?

We do not anticipate any risks associated with this study and it does not change the care your baby will receive. The results of the study will be analysed only at the end of the study, so your baby may not benefit directly from the tests. However, we hope it will help other babies in the future.

Rarely, a genetic risk factor may be identified that may have important implications for future health. In these rare circumstances, the researchers will take advice from a clinical geneticist who may recommend that you and your GP are contacted to offer the opportunity to seek further advice through a specialist genetic counselling service.

If you would like to discuss any aspect of your baby's participation in this study, please contact the Principal Investigator (contact details below). If you wish to discuss this with someone independent from the study, you may also contact the Patient Advice and Liaison Service (PALS) at this hospital.

What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you or your baby may be eligible to claim compensation without having to prove that Imperial College London is at fault. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Principal Investigator (contact details below). The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

Data protection

All data collected during this study will be handled in accordance with the Data Protection Act (1998) and NHS policies. Only researchers will have access to data and no personal information will be disclosed in any publication. The recruiting centres will enter anonymous data into a central secure database. All identifiable data will be stored safely in encrypted folders and using restricted access computers and secured servers at Imperial College London for a minimum of 10 years, as per Imperial College London policy. Paper files will be stored in locked cupboards at your local hospital and at the Centre for Perinatal Neuroscience at Imperial College London (restricted access). We ask for your permission to inform your GP about study participation and to obtain clinical data from them if needed.

Participation in future studies

We expect that the discoveries made in this project will require further research, and we request your permission to use any surplus blood samples for these studies. All such studies would be approved by a research ethics committee. We also seek your consent to gather information on your child's future health status from records held in any applicable national information system (including National Neonatal Research Database, community child health and routine hospital admission data as well as educational and social care records). We will need to use identifiable information (such as NHS number and date of birth) to link the data we hold with that of your child to do this. We also seek your permission to contact you in the future for later follow-up studies.



We will send you an annual study newsletter and would like to inform you about the study results (you can opt out at any time).

Principal Investigator at Imperial College Healthcare NHS Trust

Dr Gaurav Atreja, Consultant Neonatologist, Imperial College Healthcare NHS Trust, Hammersmith Hospital Du Cane Road, London, E mail – gatreja@nhs.net, Mobile: 07931 270686

Centre for Perinatal Neuroscience, Imperial College London

Research office telephone (9 am to 5 pm on weekdays):0203 313 2473

Study research nurse:

Josephine Mendoza, Imperial College London (j.mendoza@imperial.ac.uk), Mobile: 07915 545 603

Maria Moreno Morales, Imperial College London (m.moreno-morales@imperial.ac.uk),

Mobile: 07454 308089

Study lead:

Dr Paolo Montaldo, Imperial College London (p.montaldo@imperial.ac.uk), Mobile: 07587 945418

Chief Investigator:

Dr Sudhin Thayyil, Imperial College London (s.thayyil@imperial.ac.uk), Mobile: 07912 888 700

