

Participant Information Sheet

Road speed and physiological stability of neonates undergoing intensive care inter-hospital transfer by ambulance

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Please ask us if there is anything that is not clear or if you would like more information.

It is up to you to decide. We will describe the study and answer any questions you may have after reading the information sheet we will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This will not in any way affect the standard of care you receive.

What is the purpose of the study?

There are many environmental factors which can affect the stability of a baby during an ambulance transfer. These include factors such as temperature, noise and vibration. This study will be looking at how speed, vibration and acceleration affect the stability of the baby during an ambulance transfer by observing their heart rate, breathing and blood pressure. The purpose of this research is to understand more about the effects of motion on a baby and to help design a more comprehensive research project in the future.

What will happen during the study?

For the duration of the ambulance journey an extra sensor in the ambulance will record speed, vibration, sideways movement and acceleration / braking. This sensor will be fixed securely to the ambulance vehicle and will not be attached to or cause any risk to your baby.

The measurements from the baby will be taken from the standard monitoring equipment already on the transport incubator which are used to check the condition of your baby. There will be no alteration to the care of the baby at all and the transfer will be undertaken at a safe road speed appropriate to the condition of your baby.

The only difference is that the measurements from the baby monitor will be recorded and compared to the information about road speed and acceleration. Your baby's involvement in the study will only be for the duration of the ambulance journey.

There should be no adverse affects, disadvantages or risks to your baby by being involved in this study. The study will not benefit you in any way but may provide information to aid in improvements in care for babies in the future.

We will need to use some of the information recorded during the transfer in your babies notes but all data collected for the research will be completely anonymised and kept securely. All procedures have been approved by regulatory ethical bodies and the North West Ambulance Service. We will follow ethical and legal practice and all information will be handled in confidence.

Who is conducting the research?

This study is being carried out by Greater Manchester Neonatal Transport Service and Laura Juliet Wilkinson, a fourth year medical student at the University of Manchester. The nurses and doctors will remain responsible for the care of the patient at all times. The lead investigator is Dr Ian Dady, Consultant in Neonatal Medicine at St Mary's Hospital. His contact details can be found below.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Oldham Research Ethics Committee.

What will happen to the information collected?

All information which is collected during the course of the research will be kept strictly confidential, and will be anonymised with the removal of names, addresses and dates of birth.

The results may be used for the purpose of future research and may be published in a widely distributed medical journal. You can have access to the results of the study if you would like.

What do I do if I have concerns?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (names and numbers can be found below). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the research organizers or the hospital.

Contact details:

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THANK YOU