SHINE-2

SCREENING THE HIPS IN NEW-BORNS

Parent/Guardian Information Sheet

Chief Investigator: Professor Daniel Perry

We would like to invite you and your child to take part in our research study.

Before you decide to join in, it is important that you understand why we are doing this research study and what it would involve for you and your child.

Please feel free to talk about it with other people if you want. If there is anything that is not clear, or if you would like more information, please ask someone from the research or team.

What is the purpose of the SHINE 2 study?
The purpose of this research is to develop a new test to enhance the detection of hip problems in babies.

Why has my child been invited?
Your child has been identified following referral to the baby hip clinic as part of the national screening program for hip problems in babies.

What will happen to my child if they take part?
The assessment will involve a single additional test during your routine visit as part of the screening program that takes place at Alder Hey Hospital. In addition to the ultrasound examination, your child will have a buzzing sensor, that feels similar to an electric toothbrush, placed on their leg. Your child will lie on a special mat, which is able to 'listen' to the buzzing and interpret how the sound travels along the leg bone. This will be compared to the findings that are identified on routine ultrasound examination, which we will record for accuracy. The additional test will not influence any treatment that the hip may require.

If you have any questions relating to taking part in the study you can contact the research team directly who will be happy to discuss your child's participation further.

Do I have to take part?
No. It is up to you as to whether or not you want your child to take part in this study. Involvement in this research study is entirely voluntary, and you are free to withdraw your child at any time, without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care your child receives.

What do I have to do?
There is nothing additional that you are required to do. Should you decide for your child to participate in the study, a single additional test during your routine visit will be performed. This will take an additional fifteen minutes and does not then require any additional hospital visits.

What are the possible benefits of taking part?
There is no direct benefit to your child from taking part in this study. The reason we are doing this research is to develop a new test to try to improve the detection of hip problems for children in future.

What if something goes wrong?
The device has been tested extensively to ensure that it safe for use. The device has undergone a Portable Appliance Test (PAT test) completed by Medical Engineering Department at Alder Hey Hospital. In addition, the sounds used will be within the recommended range for new born babies. The vibration experienced will be similar to placing a buzzing electric toothbrush against the infant's skin for about 10 seconds.

This study also involves the use of your child's data. It is not anticipated that anything will go wrong in the handling of this data.

How will information that is collected be handled?
Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest'. The University of Liverpool is the main data controller and is responsible for looking after your information and using it properly.

We will be using information from you, your child and their medical records in order to undertake this study and will use the minimum personally-identifiable information possible. The data collected will be stored securely in a de-identified (pseudonymised) form. Your treating hospital will collect information from you, your child and/or your child's medical records for this research study in accordance with our instructions.

In order to contact you during the study, we will collect contact details for you and your child.

We will keep all information about you and your child safe and secure. Once we have finished the study, we will keep the data for 10 years, so we can check the results.

Your child's personally identifiable information and contact details will be stored separately to the data collected for the study.

The University of Liverpool, and your treating hospital, will use your name, health record number (e.g. NHS/CHI/H&C number) and contact details to contact you about the research study, and to make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

Individuals from the University of Liverpool, Alder Hey Children's NHS Foundation Trust and regulatory organisations may look at your child's medical and research records to check the accuracy of the research study. Your treating hospital will pass these details to the University of Liverpool along with the information collected from you, your child and/or their medical records.

The only people who will have access to information that identifies either of you will be people who need to contact you, to enable your follow-up in this study, or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, health record number or contact details.

When you agree for your child to take part in a research study, the information about their health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. This information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify your child and will not be combined with other information in a way that could identify them. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect their care. It will not be used to make decisions about future services available to them, such as insurance.

You can find out more about how we use your information:

- By contacting the study team at the University of Liverpool: SHINE2@liverpool.ac.uk
- At www.hra.nhs.uk/information-about-patients
- At https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-for-all-sponsors/.By asking one of the research team at your treating hospital
- In the Health Research Authority leaflet available from www.hra.nhs.uk/patientdataandresearch
- By contacting Alder Hey Data Protection Officer on dpo@alderhey.nhs.uk

If you wish to discuss any aspect of the way in which you have been approached or treated during the course of this study, you should contact Professor Daniel Perry who is the overall study lead on 0151 228 4811 or at SHINE2@liverpool.ac.uk, or you may contact the Sponsor at University of Liverpool at sponsor@liverpool.ac.uk.

If you are not happy with the way your information is being handled, or with the response received from us, you have the right to lodge a complaint with the Information Commissioner's Office at Wycliffe House, Water Lane, Wilmslow, SK9 5AF: https://ico.org.uk/

What will happen to the results of the research study?
The results of the study will be published in appropriate professional journals and shared with medical professionals locally, nationally and internationally in reports, at conferences and through network groups. We hope that the information we collect will, in the future, enable us to create tools or sensors that aid the detection of children's hip problems. All data will be anonymous: your child's data will not be identifiable. Data will be stored securely at the University of Liverpool and will only be accessed by nominated members of the core research team. Your data will be stored for a minimum of 10 years following the completion of this study.

If you wish, a summary of the research findings can be sent to you in a newsletter and will also be made available to you online.

Who is organising and funding the research?
This research is sponsored by The University of Liverpool. This study is funded by University of Liverpool, Alder Hey Children's NHS Foundation Trust and Liverpool John Moores University.

Who has reviewed the study?
<insert title of REC Committee>, which has responsibility for scrutinising all proposals for research on participants in this study, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your child's records in this research, together with any relevant research records, be made available for scrutiny by monitors from University of Liverpool, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

Contact for further information
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