



The Baby Hearts Study

The Northern Ireland Baby Hearts Study: a study of risk and protective factors for congenital heart disease

Participant Information Sheet

31/03/14



This study has been funded by Northern Ireland Chest Heart and Stroke.



Additional support has been provided by Children's Heartbeat Trust

We are a research team based at the University of Ulster and the Paediatric Cardiology Department of the Royal Belfast Hospital for Sick Children. We would like to invite you to take part in the Baby Hearts Study which we are conducting throughout Northern Ireland. Please take time to read the following information, which will help you decide whether or not you wish to take part.

What is the purpose of the study?

Every year in Northern Ireland over 200 babies are born with congenital heart disease. In most cases the cause of the problem is not known. The purpose of the Baby Hearts Study is to try and help understand whether environmental factors in early pregnancy increase the risk for babies to be born with heart defects. From the findings we will make recommendations which we hope will help to prevent heart defects in the future.

Why have I been chosen?

You have been invited to take part because:

- You have had a baby who was born during 2014-2016 and was diagnosed with a heart defect before they were six months old.

Or

- The baby you are expecting during 2014-2016 has been diagnosed with a heart defect.

If your baby was six months or older when they were diagnosed with a heart condition thank you for your interest; however you are not eligible to take part in this study.

What will happen to me if I take part?

If you agree to take part you will be asked to complete a short questionnaire using our iPad, or if you prefer you can complete a paper version. The questionnaire will ask you about your lifestyle, health and wellbeing, and your home and work environment in the three months before you became pregnant and during the first three months of pregnancy.

It is important that you understand that the fact that you will be asked questions about different aspects of your life and lifestyle does NOT mean that they cause congenital heart disease and certainly does not mean that they caused your baby's condition. We do not know which factors cause congenital heart disease. Many factors could be involved in causing the heart not to develop properly for any one individual baby. Also, not all babies in early pregnancy are affected by the same things.

In addition to completing the questionnaire we would also like to ask for your consent to collect some information about you and your baby from other sources. The information we would like to collect will include:

- Information collected at your antenatal booking visit which was recorded on the Northern Ireland Maternity System and in the green Maternity Hand Held Record you carried during your pregnancy
- Information about prescriptions that were issued to you and collected at pharmacies, which you may have taken during the three months before you became pregnant and the first three months you were pregnant. This will be collected from the electronic

- prescription records for Northern Ireland held at the Business Services Organisation of the Health and Social Care Board. To complete the information on prescriptions we require for the study, a clinical research nurse from the NI Primary Clinical Research Network will be sourcing information in relation to the dose and reason for a prescription for certain medications from your GP.
- Your baby's medical notes held by the paediatric cardiology team: (diagnosis and surgery)

You can decide to give consent to some or all of these. All the data guardians (those legally responsible for the data) will be assured that consent has been given before your information will be shared.

Will my taking part in this study be kept confidential?

All personal information collected about you will be kept strictly confidential. The answers you give in the questionnaire and the information obtained from your health records will be stored electronically, in password protected format, with only your study ID number attached. Your personal details form and consent form (which the researcher will show you) will be kept separately and securely as paper records only, until the end of the study. Only the authorised researcher team will have access to your data. All data storage and processing will be in accordance with the Data Protection Act (1998).

We will not disclose any information that you have shared with us to your GP, maternity or clinical team. We are required by law to report anything you disclose that is illegal or an imminent threat to life, however our questions do not cover such matters.

In accordance with current University of Ulster regulations all anonymised data will be stored securely for ten years before being destroyed using secure methods.

Do I have to take part?

Participating in this study is completely voluntary. If you agree to participate in this study, you will be asked to sign a consent form indicating your willingness to participate in this research and you will be given a copy to keep. If after deciding to take part, you wish to withdraw you may do so at any time without giving a reason. Your decision will not affect the care of you or your baby. If you withdraw from the study, information collected to date will be used unless you specifically ask for it to be deleted, but no further information will be collected.

What are the possible benefits of taking part?

There is unlikely to be any particularly direct benefit to you but you may feel that your participation will contribute to a greater understanding of the causes of babies being born with a heart defect. If you would like to have a copy of the findings once the study is completed please tell the researcher or Nichola McCullough (see at the end for contact details).

What are the possible disadvantages of taking part?

There are no obvious disadvantages or risks to taking part in the study. It is possible that you may find it uncomfortable to answer some questions. You do not have to answer anything that

you feel uncomfortable with. It is also possible that answering some questions may reveal an anxiety or worry that you may have about you or your baby. If this happens please let us know and we will arrange for you to speak to a nurse or your clinician.

Token of Thanks

To say thank you for taking part in our study we would like to give you a gift token for £10 that can be used in a number of high street shops.

What if there is a problem?

If you have any concerns about the study please speak to Nichola or any member of the research team (details are provided below) and we will do our best to answer these. If you are still unhappy, the University of Ulster also has procedures in place for reporting, investigating, recording and handling complaints from study volunteers. Further information on the complaints procedure can be found at the University's "Research Ethics and Governance" webpage (<http://research.ulster.ac.uk/rg/0208ResearchVolunteerComplaintsProcedure.pdf>).

A formal complaint may also be made through the Belfast Trust. They will have a complaints procedure and you can obtain these details from the Complaints Department Tel: 028 95048000 or Email: complaints@belfasttrust.hscni.net

What will happen to the results of the research study?

This study will take place over three years. When completed, the results will be presented to medical teams and other health professionals with responsibility for care of children with heart conditions and for public health. The results will also be presented at local, national and international conferences and in scientific journal publications. You will not be identified in any report or publication.

Who is funding this study?

The financial support for the study has been granted by Northern Ireland Chest Heart and Stroke, and The Children's Heartbeat Trust.

Who has reviewed this study?

This study has been reviewed and has been given a favourable opinion by the Northern Ireland Research Ethics Committee. An external review process administered by the Northern Ireland Chest Heart and Stroke reviewed the scientific basis of the study before the researchers were awarded funding.

The members of our external advisory committee, who will continue to advise until the end of the study, are:

Ms Zoe Boreland (Midwife)

Ms Katie Boyd (Parent)

Dr Tabib Dabhir (Medical Geneticist)

Ms Heather Reid (Public Health Consultant)

Dr Chris Tennyson (Clinical Psychologist)

The Northern Ireland Baby Hearts Study Project Team

Royal Belfast Hospital for Sick Children:

Dr Frank Casey; Dr Brian Craig, Dr Sinead Callaghan

University of Ulster:

Professor Helen Dolk, Dr Briega M Lagan, Dr Maria Loane, Dr Nichola McCullough, Professor Brendan Bunting, Dr Breidge Boyle, Dr Hafi Saad (PhD student)

Further information and contact details

If you would like to discuss any aspects of the study, or would like to ask any questions or have concerns about the study, please contact either:

Project Manager: Dr Nichola McCullough,

Research Fellow, University of Ulster

Tel. 028 903 68053 or Email n.mccullough@ulster.ac.uk

Chief Investigator: Professor Helen Dolk,

Professor of Epidemiology and Health Services Research, University of Ulster

Tel. 028 90366639; Email h.dolk@ulster.ac.uk.

Thank you for taking time to read this information sheet and for considering taking part in our study.



 **Belfast Health and Social Care Trust**



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 **South Eastern Health and Social Care Trust**

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Quality Care - for you, with you

 **Western Health and Social Care Trust**