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Parent Information Sheet and Consent Form Invitation to screening visit

FULL STUDY TITLE: **Respiratory Health Outcomes in Neonates (RHINO)**

CHIEF INVESTIGATOR: **Professor Sailesh Kotecha** (University Hospital of Wales, Heath Park, Cardiff)

Introduction

You may recall that you kindly completed a questionnaire for us in 2013 on the breathing and development of your child. When you completed the questionnaire, you were happy for us to contact you to consider participating in future studies.

We are now inviting you and your child to take part in a further research study. Before you decide if you want your child to take part, it is important that you understand why the research is being done and what it will mean for you and your child. Please take time to read the information leaflet. Please feel free to talk to others about the study and please ask us any questions that you may have or if anything is not clear.

What is the purpose of the study?

We know that children who are born prematurely have breathing problems like wheezing (“whistling in their chest”) or shortness of breath but we do not know why children born prematurely have these breathing symptoms. Our first questionnaire study showed that many prematurely born children have symptoms affecting their breathing but we do not know if they improve with time.

Sometimes it is said that these children have asthma but our research shows that children

born prematurely may have different reasons for their symptoms. The overall aim of the research is to understand why children born prematurely develop breathing symptoms and to identify the best treatment for these children. We would therefore also like to perform breathing tests and analyse samples from the breathing tubes, such as saliva (spit) and sputum (phlegm), to understand the possible reasons why prematurely born children develop breathing problems. We do not know if medicines used to treat asthma work in children who are born prematurely so we are aiming to identify the best treatment for these children.

Why has my child been chosen?

We would like to invite you and your child to participate in two parts. You may wish to participate in one or both parts:

Firstly, you may recall that you kindly completed a questionnaire for us in 2013 on the breathing and development of your child. We would like to invite you again to complete the enclosed questionnaires to see how your child’s symptoms have changed over the last 2 – 3 years.

Secondly, we would like to visit your home to learn more about your child and their breathing problems and/or symptoms.



What will happen to my child if we agree to take part and how long will it take?

For the **first part**, please complete the enclosed questionnaire and return it to us in the pre-paid envelope.

Please do not hesitate to contact the RHiNO team on telephone 029 2074 4187 or by email (rhino@cardiff.ac.uk) if you have any questions.

For the **second part**, a research nurse or doctor will visit your home. This should take about 60 – 90 minutes. If you prefer, you can opt to attend a clinic visit at the Children's Hospital for Wales, Cardiff. The nurse or doctor will explain the research in detail and give you an opportunity to ask any questions. If you are satisfied with the explanations, you will be asked to sign a consent form agreeing to take part. If your child is also happy to take part, they will be asked to sign an assent form. You will be given a copy of this information sheet and your signed consent and assent forms to keep.

Once consent has been given, you and your child will be asked questions about their general health (including any medication your child is on). There is a short questionnaire for your child to complete on how they are feeling at the time of the visit, and the doctor or nurse will also review your questionnaire responses from part 1 of the study. They will also do a quick examination, including taking your child's temperature, to make sure they are OK to take part. This will include asking about your child's stage of puberty by using a questionnaire for girls (to be completed by you and/or your child); for boys we shall ask your child or you to estimate the size of their testicles by comparing to an 'orchidometer'. The nurse/doctor will then measure your child's height, weight and body composition (how much muscle and fat they have) by standing on weighing scales. A cardiovascular assessment will also be performed which is very similar to taking a blood pressure but also needs an extra cuff to go around your child's thigh as well as their upper arm - this will only take a few minutes.



Next, the nurse or doctor will do breathing and blowing tests (called lung function and exhaled nitric oxide or eNO) to see if your child has any signs of narrowing or redness (inflammation) in the airways. We will demonstrate the tests to your child and let them practise before doing the final tests. After the breathing tests, the nurse or doctor will give the medicine called salbutamol using an inhaler, before repeating one of the breathing tests to see if the medicine has any effect. This medicine is commonly used in children who have asthma. The most common side effects are an increased heart rate and headaches. We do not expect these to happen often, but we will check to make sure your child is OK.

We would like to collect a urine sample during the visit to check your child's exposure to other peoples' cigarette smoke and to test for agents that may be increased in lung diseases. We would also like to collect a sample of your child's saliva (spit) so we can look at their genes (DNA) and other factors which we think are important for breathing problems and for response to different medicines. The saliva sample is optional and it is OK if you would prefer for your child not to provide it – your child can still take part in the rest of the study.



Does my child have to take part?

No, taking part is completely voluntary. It is up to you and your child to decide whether or not to take part. Even if you do agree to join, you can stop at any time without giving a reason. A decision to leave the study, or a decision not to take part, will not change the standard of care you and your child receive now or in the future. If you do take part, you will be given this information sheet to keep and be asked to sign a consent form.

What are the other possible disadvantages and risks of taking part?

We do not feel there are any disadvantages and risks of taking part in the research.

As professionals, we are required to report any findings to the appropriate agencies if we observe anything of concern during the home visit. Our researchers will discuss any concerns with you before taking any action, if appropriate.

What are the possible benefits of taking part?

We are conducting this research so that we know how best to treat children born prematurely who have breathing problems and symptoms. Taking part will not help your child personally but the information we get might help to improve the treatment of children who were born prematurely in the future.

What will happen if my child or I don't want to carry on with the research?

You or your child can withdraw at any time, if you wish. All data collected up until the time of withdrawal will be anonymised (this means that a number will be used instead of your child's name so that no-one will know the information is about them) and included in the study analysis, unless you specifically state otherwise.

What if there is a problem?

If you have any questions about the study, please contact Professor Sailesh Kotecha or Dr Michael Cousins. If you are still unhappy after you have spoken to them and wish to complain formally, you can do this through the

NHS Complaints Procedure. In the event that something goes wrong and your child is harmed during the research study, there are no special compensation arrangements. If your child is harmed due to someone's negligence then you may have grounds for legal action. However, you may have to pay your own legal costs. The normal NHS complaints mechanism will still be available to you.

Will my child's taking part be kept confidential?

Yes. All of the information about your child's participation in this study will be kept confidential.

All information that is collected about you and your child during this study is considered to be confidential and giving this information to someone else ('a third party') is not allowed with the exceptions noted below. The paper files used to record information in this study will be labelled with a unique study number. Medical information may be given to your child's doctor or appropriate medical personnel responsible for their welfare.

If you and your child join the study it will be necessary for members of the North Wales Organisation for Randomised Trials in Health (NORTH), representatives of regulatory authorities, and authorised people from other NHS bodies to check that the study is being carried out correctly. Your child's records will be checked on site and will not be removed. All authorised individuals have a duty of confidentiality to you and your child as research participants and nothing that could reveal your child's identity will be disclosed outside the research site. By signing the consent form you are giving permission for these checks to happen. In the event of the results of the study being sent to Health Authorities or published, all of your child's records will be kept confidential and your child's name will not be disclosed to anyone outside of the study. All documents and files relating to the study will be stored confidentially for a maximum period of 25 years.

What will happen to any samples my child gives?

All samples (saliva, urine) will be sent to the Department of Child Health at Cardiff University for testing in our laboratory. Some tests may be conducted by commercial companies or other university laboratories which have expertise to analyse the samples. The samples will have a code which means they will not be linked to information about your child.

With your permission any remaining samples, including DNA, may be stored for future research into comparing children who were born prematurely and those who were born at term. The samples will be anonymised before use in future studies and may be accessed by researchers in the UK and abroad; the research may include genetic (e.g. DNA) and commercial research. You may withdraw your consent for the storage and future use of your child's samples at any point. If you do withdraw your consent your child's samples will not be used in any subsequent studies and will be destroyed according to locally approved practices at Cardiff University.

Any samples already distributed for use in research prior to the withdrawal of consent will continue to be used in that study and any samples remaining at the end of the study will be destroyed.

What will happen to the results of the research study?

The results will be published in medical journals and presented at medical conferences. Your child's confidentiality will be ensured at all times and they will not be identified in any publication. At the end of the study, the results can be made available to you (should you wish). They will also be published on the RHiNO website.

Who is organising and funding the research?

The study is sponsored by Cardiff University and funded by the Medical Research Council (MRC). Cardiff University have assigned the management of the study to the North Wales Organisation for Randomised Trials in Health (NORTH) at Bangor University.

Who has reviewed the study?

The study was approved by the South West-Central Bristol Research Ethics Committee (Ref 15/SW/0289). It has been registered with the International Standard Randomised Controlled Trial Number ISRCTN14767962.

Contact details:

Please do not hesitate to contact the RHiNO team on telephone 029 2074 4187 or by email (rhino@cardiff.ac.uk) if you have any questions. Further information is available at our website <http://rhino-health.org>.

Thank you for reading this information sheet



Parent/Guardian Consent Form

RHiNO: Respiratory Health Outcomes in Neonates (Part 1)

<p>1 I confirm that I have read and understood the information sheet dated 'Version 5 21/09/2016' for the above study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily.</p>	Initial:	
<p>2 I understand that my child's participation is voluntary and that we are free to withdraw at any time, without giving a reason, and without my child's present or future medical care or legal rights being affected.</p>	Initial:	
<p>3 I understand that relevant sections of any of my child's records and data collected during the study relating to my child may be looked at by responsible individuals from the sponsor, funder, regulatory authorities or hospital. I give permission for these individuals to have access to these records where it is relevant to taking part in this research.</p>	Initial:	
<p>4 I agree that personal identifiable information will be collected, stored and used to enable follow-up of my child. This is on the understanding that all information will be treated confidentially.</p>	Initial:	
<p>5 I agree to my family doctor being informed of my child's participation in the study.</p>	Initial:	
<p>6 I agree to allow my child to take part in the RHiNO study (part 1).</p>	Initial:	
<p>7 Optional: I agree to allow a sample of my child's saliva to be taken for use in this study, which will include genetic (DNA) research.</p>	<p>YES NO Please circle</p>	Initial:
<p>8 Optional: I agree for any remaining samples to be used in future for research into children who were born prematurely in the UK and abroad which may include genetic (DNA) and commercial research. I understand I am free to withdraw my consent to future research at any point and that all samples will be destroyed as detailed in the information sheet.</p>	<p>YES NO Please circle</p>	Initial:

Name of Child:

Name of Parent:

Signature:

Date:

Researcher:

Signature:

Date:

Original for case notes, 1 copy for parent/guardian, 1 copy for investigator site file