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Burden of RSV Disease

Study Information Booklet

You are invited to take part in a study to determine the burden of disease due to Respiratory Syncytial Virus (RSV), the commonest virus causing coughs,colds and chest infections in young children. The study is being run by Oxford University Hospitals NHS Foundation Trust and the Oxford Vaccine Group (OVG) which is part of the University of Oxford.

Before you decide whether to take part, it is important for you to understand what the study is about and what participation would involve. Please take time to read the information carefully, and discuss with others if you wish. If anything is unclear or you would like further information please contact the study team (details below).

Thank you for taking the time to consider taking part in the study.

Who are the Oxford Vaccine Group?

The Oxford Vaccine Group is part of the University of Oxford and is an independent research team of doctors, nurses and play assistants. We carry out research studies on infectious diseases and vaccines for babies, young children, teenagers and adults and teach doctors and nurses about immunisations. In the past 5 years alone, over 7000 participants in the Thames Valley area have taken part in our research studies.

Why have I been approached about the study?

You have been approached about the study because either;

- You are pregnant and are attending appointments in an area that is taking part in this research study

Or

- You have recently given birth to a healthy infant born at 37 weeks of gestational age or later

This study intends to recruit 2000 new-borns across the Thames Valley and South Midlands' area.

What is Respiratory Syncytial Virus (RSV) and why is it important?

RSV is the commonest virus causing coughs, colds and chest infections in infants. More than half of children will be infected in the first year of life, mostly during the winter. Most infections are mild (runny nose, cough and cold), but in some cases infants develop a severe chest infection requiring admission to hospital. In the winter months, RSV is responsible for around 1 in 6 of all hospital admissions in infants in the UK. Worldwide, RSV is the second largest cause of death in children under one year of age after malaria, mostly in Africa and Asia. In addition, about half of children who develop an RSV chest infection go on to have symptoms of asthma, including wheezing and coughing, for the next few years. Currently, there is no curative treatment or vaccine for prevention of RSV.

What is the purpose of the study?

The main purpose of this study is to determine the burden of disease due to Respiratory Syncytial Virus (RSV) in young children. It aims to understand how frequently children are infected with RSV, which children are most severely affected

and what symptoms continue in the years after an infection. The study also aims to see if we can find out whether a child is more likely to have severe RSV infection or have longer lasting symptoms by looking for certain indicators called biomarkers. These biomarkers can be found in blood, mucous, other body fluids and in the DNA. The DNA contains the genetic instructions that are transferred from parents to their children which determine the child's characteristics, such as how tall they are or the colour of their eyes.

Will my child be eligible for this study?

Your child can participate in this study if he or she is/was born at at 37 weeks of gestational age or later, is less than 8 days old and does not have any severe medical conditions.

Does my child need to take part in this study?

Taking part in this study is completely voluntary and if you decide to say no, it will not affect your child's routine care in any way. You are also free to change your mind and withdraw your child at any time without giving an explanation.

What happens in the study?

If you decide you would like to take part in this study, a member of the research team either from the hospital you are attending or from the Oxford Vaccine Group (OVG) would talk you through the study and answer any questions you may have before asking you to sign a consent form.

If your baby hasn't been born when you sign the consent form, we would ask your permission to access your medical records to track when you give birth. A member of the research team will then make contact with you to confirm you still wish to take part. A visit would be scheduled with you either in the hospital, or at home (by a member of the OVG research team).

Birth

Doctors or nurses from the research team would ask questions about your health and the delivery of your baby. Information about the delivery may also, with your permission be taken from you and your child's medical records.

To help us understand what happens when a child becomes unwell with RSV infection, we need to take samples before the child comes into contact with any infections or becomes unwell (baseline). For 200 newborns, we would collect samples of blood, urine and stool and nose and mouth swabs at around the fifth day of life (below is more detail about how these are collected).

Weekly contact during RSV season (October – May)
There would be weekly contact with the study team, by email or phone from October – May to ask about any colds or chest infections. Every time your child has a cold or chest infection, a doctor or nurse would visit you at home and take two nose swabs to test if the infection is caused by RSV.

Collection of samples in the event of RSV infection
At the first RSV infection we would collect more blood, urine and stool samples and another nose swab. We would then come and visit you again 7 weeks later when your child is better to collect the same samples.
These samples would help us understand what is happening in your child's body when they become unwell with RSV infection and can be compared to the samples we took at birth.
If RSV is identified a second time no further blood, urine or stool samples will be taken.
If RSV is never identified no further blood, urine or stool samples will be taken.

Yearly Questionnaires
We would follow up your child every year by asking you to complete a questionnaire about your child and your family's health. The study will run for 3 years and if you decide to take part, we will be able to tell you how many years you and your child would be followed up for, although it would be for a maximum of 3 years.

How are the samples collected?

All samples would be collected at birth and then twice more if your child were to become unwell with an RSV infection.

Blood samples

The amount of blood we take would depend on the age and weight of your child but would be less than 5ml (a teaspoon). For the blood tests, anaesthetic cream is used to numb the skin. There will also be a second person to help distract the child. If it is not possible to get the full amount of blood after one attempt, we would ask your permission to have a second attempt.

Nasal samples

Samples of nasal mucous would be collected using a swab, which looks like a cotton bud. The swab is passed to the back of the nose as shown below; this can be a bit tickly but will only take a few seconds.

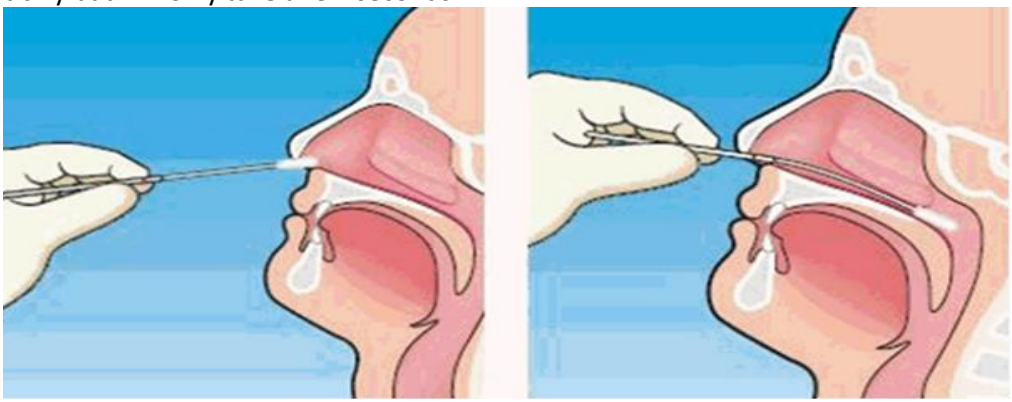

Image taken from: www.thenurseszone.com

If your child has enough mucous that we can see e.g. when they are unwell, we can collect it without passing the swab to the back of the nose.

Mouth swab (Cheek)

A sample from the lining of the cheek is collected by scraping a soft brush against the inside of the cheek.

Urine and stool samples

These can be collected from your child's nappy. It is possible that a member of the research team will not be present when there is a sample to collect, so we would give you instructions and some gauze or cotton wool to collect them yourself. We would then provide you with a container and ask you to store them in your freezer at home until they can be collected.

What are the possible risks and discomforts of taking part in this study?

There are few risks of participating in this study. Blood and respiratory sampling can be associated with minor local effects, for example, discomfort, bruising or nose bleeds. There are no risks associated with collection of urine or stool samples.

What are the benefits of taking part in this study?

By taking part in the study your child will not have a direct benefit, nonetheless, other children may benefit in the future from what is learned in this study. If your child were to develop a respiratory infection, you would know if it was due to RSV.

What will happen to my child's samples?

The samples we take for this study will be labelled with a study number, not your child's name. Samples will be tested anonymously in certified laboratories, including those outside Europe. If you choose to take part in this study, we will be asking for your separate permission to store samples taken in a collection called a Biobank. Details of this will be provided in a separate booklet after you are enrolled into this study. You are free to say no to the biobanking of samples but continue to take part in this study. If you do not want your child's samples to be stored in the Biobank, they will be disposed of at the end of the study.

Would my child's taking part in this study be kept confidential?

Any research study records with you or your child's name and address would be held confidentially by the research staff in the hospital you attended. When you have been discharged from the hospital, the research study records (which are different from NHS medical records) will be transferred confidentially to the OVG research team, who will continue the care of your child in this study.

All the information collected for the study will be coded with a study number and kept strictly confidential. Only authorised study staff can access you or your child's data. No data that identifies you or your child will leave the research sites (local hospital or OVG). Following completion of the study, all study records (which includes some personal data such as name, date of birth and contact details) will be retained up to 3 years after the youngest participant reaches 18 years of age. We would also seek your permission to use the data in future related research. Files will be confidentially destroyed if storage is no longer required.

By signing the consent form for this study, you would be giving permission for the research staff in your local hospital and OVG, representatives of the Sponsor (Oxford University) and appropriate regulatory authorities to look at you and your child's medical records and study records.

We will inform your child's GP and health visitor that s/he is taking part in this study.

Who else can see my child's study records?

In order to ensure that the study is being conducted correctly the study records can be inspected by the Clinical Trials and Research Governance Office (CTRG), University of Oxford, without violating yours child's confidentiality. This group is responsible for ensuring the appropriate conduct of the research on behalf of the research sponsor (the University of Oxford).

The RESCEU Consortium

This study is part of a wider group of studies all trying to understand the burden of RSV infection. In total 10,000 children will be enrolled in countries across Europe. Experts from Universities, hospitals and laboratories have formed a group called RESCEU (Respiratory Syncytial virus Consortium in Europe) to carry out these studies and test the samples. The anonymised data and samples collected from you and your child will be combined and shared with the group of experts to help understand the burden of RSV infection in Europe. Neither you nor your child will be identifiable from the data shared with the consortium. The anonymous electronic data will be stored on a secure server held by the University of Utrecht (a partner of the RESCEU consortium).

Who is organising and funding the research?

The study is funded by the Innovative Medicines Initiative (IMI), which is a joint undertaking between the European Union (EU) and the pharmaceutical industry association (EFPIA), and is being sponsored by University of Oxford.

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

You can change your mind and withdraw your child from the study at any time without giving any reason. If you change your mind and withdraw your child from the study we would use the samples and data we have collected up until the point you informed us that you wanted to withdraw, unless you inform us in writing that you wish for your child's data and samples to be destroyed.

What will happen at the end of the research study?

You will receive a summary of the study results when the study ends. To allow for full analysis of all participants' data, this information will be released about one to two years after the last child completes their participation in the study.

All OVG publications will appear on the OVG website and you will receive a letter summerising these results. Your child would not be identified in any report or publication and we will not provide individual results.

If you are interested in hearing about other research studies that we may be running in the future then there is an option to sign up to a contact list through which we can get in touch. This does not oblige you in any way to take part in the future research.

What if I wish to complain?

If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, you should contact the Oxford Vaccine Group on 01865 611400 or email info@ovg.ox.ac.uk. You can also contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224 or email the Head of CTRG Heather House ctrg@admin.ox.ac.uk . Alternatively, you can contact the Patient Advice and Liaison Service (PALS) in your local hospital on 01865 221473 or email PALS@ouh.nhs.uk.

What if something goes wrong?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that your child suffers any harm as a direct consequence of participating in this study.

What else do I need to know?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participant's interests. This study has been reviewed and given favourable opinion by South Central - Oxford B Research Ethics Committee.

So in summary:

- This study will help to determine the burden and frequency of RSV infection, identify which children are most severely affected, and try to find a way to predict if a child is more likely to have severe RSV infection or have longer lasting symptoms.
- 200 newborns will be followed closely; with samples taken in their first week of life, frequent contact with a research nurse or doctor and annual questionnaires from birth up to a maximum of their third birthday.
- Additional home visits will be undertaken in children who experience colds or respiratory infection during the first year of life. If such colds are due to RSV, samples will be taken at the time and again 7 weeks later.

What do I do now?

You do not need to make a final decision straight away. Please contact us by:

Calling the Paediatric Research Team at the Children's Hospital:

- Telephone: 01865 231729
- Email: childrensresearch@paediatrics.ox.ac.uk

Or by contacting the Oxford Vaccine Group

- Email: info@ovg.ox.ac.uk
- Telephone: 01865 611400
- Website: babyrsv.org

Members of the research team will be happy to discuss the study with you and answer any questions you may have.
Thank you for considering taking part in this study.
Yours sincerely,

Dr Matthew Snape
Chief Investigator
Consultant Vaccinologist and Paediatrician
Honorary Senior Clinical Lecturer

Dr Simon Drysdale
Principal Investigator