Bradford Teaching Hospitals
NHS Foundation Trust

BaBi - RSV-immune:

A sub-study of BiB4All

Background

As part of BiB4All we are already linking together routinely collected data to build a clearer picture of people's lives, and to explore the relationship between the development of babies in pregnancy and children's future health. We are now hoping to build on this and understand more about a specific virus called Respiratory Syncytial Virus (RSV).

What is RSV?

RSV causes a highly infectious lung illness which is a common cause of infection in babies and children. RSV tends to cause infections in children about once a year and every few years in adults. For most people, RSV causes a cold-like illness. RSV can sometimes cause serious illness, hospitalisation and in some cases death. People from minoritised ethnic groups may be more at risk of RSV including families from Asian and Black backgrounds. Children experiencing poverty may be at higher risk of severe disease. Babies born prematurely or with other health conditions are also at higher risk of severe illness. In 2024, a new vaccination for RSV was introduced in the UK and is offered to women from 28 weeks of pregnancy. The vaccine works by producing antibodies in the mother that are then passed naturally to the baby to give them protection against RSV in the first months of life.

What is this study looking at?

We are interested in understanding more about you and your child's immune system protection against RSV, to help understand how we can best prevent RSV in future and improve the new RSV prevention programme. We are interested in understanding how much immunity mothers and babies in Bradford have against RSV. Immunity is your natural protection against an illness. Immunity can be developed in different ways, including the natural protection your body produces in reaction to having an illness as well as protection delivered by vaccination.

This study aims to understand how babies receive protection from their mothers. We are looking at how much antibodies can pass from mother to baby during pregnancy, and, at some sites, whether antibodies in breastmilk may also help protect babies after birth.

We want to understand how different immunity is if you have or haven't received the RSV vaccine, and if you have had the vaccine, how different immunity is based on when you had it. We also want to understand how immunity is different if your child is or isn't born prematurely.

Who can take part in the study?

Most people who are part of BiB4All and are either pregnant or had a baby up to 7 days ago can join the BaBi-RSV study. We are not able to include people who have a serious, significant immune problem or those taking chemotherapy or similar drugs.

What happens in the study?

There are two parts to the study. Each part should take no longer than 1 hour to complete.

- **Part 1**

  Collecting samples from mums and babies around the time of birth to look for RSV immunity
- **Part 2**

  Collecting samples from babies at 6 months old to look for RSV immunity

There will also be a short questionnaire to complete about you and your baby's health, and more general information about your household. You can choose to complete this yourself or we can help you to fill it in.

What samples will be taken?

To help us understand how RSV immunity changes over time, we will take a small sample from both you and your baby at two time points; around the time of birth and when your baby is about 6 months of age.

- **From you**

  A blood sample and a swab from your nose will be taken from 36 weeks of pregnancy up until 2 weeks after you give birth. This might be during routine blood collection for your clinical care or separately by the research team. Some women may be asked to provide a small sample of breast milk, approximately 5 ml (about one teaspoon). This would only be requested if you are already expressing milk for your baby and are likely to be in hospital for a period of time, for example if your baby is being cared for on the neonatal unit.

- **From your baby**

  A blood sample will be taken from the umbilical cord after you have given birth and then again from your baby at 6 months of age. To minimise any distress caused by the procedure we will use anaesthetic cream to help numb the skin for the test at 6 months. A swab from your baby's nose or mouth will also be taken at both times.

How is the cord blood sample collected?

Mother and baby are not affected by the umbilical cord sample collection. After your baby is born and the umbilical cord has been cut there may be some blood remaining in the bit of the cord that is still attached to the placenta. Before the placenta and the umbilical cord are discarded, we would like to collect a sample of the leftover blood that would otherwise be wasted, if there is any remaining after any clinical tests have been completed.

How will you take other samples?

Where possible, all samples will be taken at the same time as other samples you or your baby are having done for your usual health care, or from the umbilical cord after you have given birth. Wherever possible, we will coordinate with your midwife, paediatrician, or with your routine care team to use leftover samples taken for your clinical care (for example, from routine antenatal booking blood tests or blood tests taken during hospital care when a cannula is inserted for another clinical reason) to avoid unnecessary samples.

If an umbilical cord blood sample is not possible, we may take a small (less than a quarter of a teaspoon) heel prick sample instead, before your baby is 7 days old. If this is not possible, we may take a small blood sample from a vein using a tiny needle, performed by trained and experienced professionals. We will only have a maximum of 2 attempts to obtain the blood, and you would have the final decision to proceed with a second attempt if the first was unsuccessful.

For the nose swabs, a small piece of absorbent paper will be placed just inside the nostril for up to 60 seconds. Some mothers may be asked to share a small breastmilk sample after their baby is one week old. The amount is very small: about one teaspoon (5 ml). You will only be asked if you are already expressing breastmilk and feel comfortable providing an extra sample. The sample can be given at a time that suits you, using your expressed breastmilk.

What happens with the samples?

The samples will be labelled with a sample identification number and taken to the laboratory at Bradford Royal Infirmary to be processed and stored securely in the BiB4All Biobank. The Biobank or pathology labs are special storage facilities for biological samples like blood or urine. This will then be sent to our research partners in Oxford and UK Health Security Agency (UKHSA). Our research partners in the UK, Europe and other areas can also apply to use the samples for related research questions. This may include health research involving analysis of genes and DNA. There will be no individual results that can be fed back to you.

Do I have to take part?

You do not have to take part. Taking part in this research is completely voluntary. If you decide to say no then you and your child's regular care from your midwife, doctor or nurse will not be affected in any way.

You are also free to change your mind and withdraw at any time without giving an explanation. If you decide to withdraw, it will not affect your or your child's care and you can request your data and samples to be destroyed.

What are the risks or discomforts of taking part for me and my baby?

Taking blood and mucosal swabs may sometimes cause bruising at the place where the needle or swab goes into the skin, nose or mouth. This can cause some soreness or pain. More rarely, fainting or infection may occur.

What are the benefits of taking part?

There are no immediate benefits for you or your baby in taking part in the study. We hope that the results from the study will help us understand more about RSV and how we can best prevent illness and improve protection in the population. If you choose to take part, you will receive a £25 voucher after completion of part 2 as a thank you for your time.

How will you keep information confidential?

When you take part, you will be given a unique study number and only authorised members of the study team will be able to identify you from your study number. Your sample will be stored securely in our biobanks and in strict confidence using this study number. Your questionnaire answers will be stored securely and separately from your name and other personal information to make sure that your answers are anonymous.

Why should I take part?

While there is no direct benefit to you or your child, we hope that we will gain new knowledge to improve the health of children in the future in Bradford and beyond. Taking part is entirely voluntary and it is up to you whether you decide to take part. If you don't want to take part, just let us know. It won't affect the care you receive. If you change your mind later, contact us and any samples left over will not be used for further research.

We hope that this study will help us to understand how to protect premature babies against RSV bronchiolitis and lung infections, and how we can provide better care and protection against RSV for all babies.

Who is conducting the study?

This study is being run as a sub-study within the wider BaBi study by a collaboration of members of the BaBi study team, Oxford University, and the UK Health Security Agency. One of the study team, Dr Jonathan Broad, will be using some of the analyses as part of a PhD study at the University of Oxford. The study has been reviewed by the Health Research Authority (HRA) and Leeds Bradford NHS Research Ethics Committee (REC) who have considered whether the conduct of the study is legal and ethical. The study has been given favourable opinion REC ref: 17/YH/0202.

Who is funding the research?

This research is receiving financial support from the UK Health Security Agency, who are funding the cost of laboratory analysis. The University of Oxford are funding student costs for one of the research team, Dr Jonathan Broad. Core support for the salary of study team members is being provided by the Bradford Institute for Health Research. Research nurses and midwives working on the study are being funded by the National Institute for Health and Care Research and the British Medical Association Foundation. The study is not receiving funding from any commercial providers.

If you wish to take part

If you are interested in joining this sub-study, a member of the study team will discuss the study further with you in person during your routine care or via the telephone. We will answer any further questions that you may have, check for any health conditions, and complete the consent form if you wish to go ahead and join.

What happens when the sub-study stops?

When the sub-study stops, you and your child will continue to be participants of BiB4All. After all participants have completed their visits, the study will continue whilst the analysis and interpretation of the results continues.

Once this is complete, the results will be written into a publication, that will be published. Some of the results will also be written into a PhD study, which will be published. We will notify you of the results of this publication and provide links to the paper. This can take three years after the visits have been completed. We will list the publication on the BaBi/BiB website.

How will we use information about you?

We will keep all information about you safe and secure. Bradford Teaching Hospitals NHS Foundation Trust is the sponsor organisation responsible for the initiation, management and arranging the funding of a research project. We are also responsible for looking after your personal information. In order to store your samples and use them in research studies, we will need to use information from your hospital patient record about you and your baby. This information will include your name, NHS number and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details.Your data will have a code number instead.
Once we have finished the study, we will keep some of the data until 15 years after the completion of the study so that we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have and will analyse this anonymously. If you wish, you can specifically request for us to delete these data.
We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

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

- By visiting: https://borninbradford.nhs.uk/privacy-policy/
- By asking one of the research team
- By sending an email to borninbradford@bthft.nhs.uk or
- By ringing us on 01274 274474.

You can also find information about how your data is used on the Health Research Authority website here: http://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/bib4all/

What next?

If you have decided that you wish to take part in the study, simply register your interest online via email borninbradford@bthft.nhs.uk or call us on 01274 274474 and we will arrange the next steps.

Contact Us

If you have any questions about the study please use the contact details above to get in touch with the study team.

Complaints

If you have any complaints or concerns, please contact us by:
Email: borninbradford@bthft.nhs.uk
Write to us: Born in Bradford Office Bradford Institute for Health Research Bradford Royal Infirmary Duckworth Lane Bradford, BD9 6RJ or by ringing us on:
Telephone: 01274 274474

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