

Parent Information Leaflet

Neonatal complications of coronavirus disease (COVID-19) study

This leaflet provides information about a new study of coronavirus disease, (COVID-19), in newborn babies.

What is coronavirus?

Coronavirus is a viral infection that usually affects the lungs and airways. The current virus is a new type of respiratory virus and causes the disease COVID-19. Like many viruses, it can affect all age groups including mothers and their newborn babies.

Why is this study important?

This study is needed to understand the impact of Coronavirus infection in newborn babies and babies born to mothers with Coronavirus, so we can improve the care we give them.

We know this new virus is very infectious so can spread easily. In adults, particularly the elderly, it can cause significant breathing problems requiring treatment. So far there is little information about what happens to newborn babies if they get this infection, or how it affects babies born to mothers with the virus. We don't know if certain babies are at greater risk and don't know which treatments may or may not help in these babies.



What are the aims of this study?

Throughout the United Kingdom we will collect information about babies born to pregnant women who develop coronavirus around the time of birth and where the baby is unwell and needs neonatal care in the first four weeks after birth

We have three main aims:

1. Find out how many babies develop coronavirus infection in the first month after birth, and how many babies born to women with coronavirus need neonatal care. We will also find out what happens to babies to improve our understanding of this virus, how best to manage it and what the impact of infection is for babies as they get older.
2. Describe which babies develop COVID-19 infection and what symptoms or signs they have. This will help us to design future research looking at prevention and new treatment options.
3. Describe how COVID-19 in babies is identified and treated.

How long will the study last and where is it happening?

This study will last for 13 months from March 2020 and will take place across England, Scotland, Wales and Northern Ireland.

How will the information be collected and used?

The University of Oxford is the sponsor and data controller for this research study so is responsible for looking after the information and using it properly.

We will collect information about babies with a new diagnosis of COVID-19, or in babies needing hospital care if born to a mum with the infection. Doctors who are looking after the babies will provide the information, but not their names or addresses. They will provide details like NHS number, sex, ethnic group and date of birth. The doctors will complete questionnaires using information from medical records. We will cross-check the information with other NHS databases to make sure we don't miss any affected babies.

The smallest amount of personally identifiable information will be used. We cannot totally remove personal information from the study as this would make the research meaningless. When the study finishes, personal information will be deleted or de-identified. The University of Oxford will securely store the study information for at least 5 years.

For more details about how personal information is used in the study, please see the study website: <https://www.npeu.ox.ac.uk/pru-mnhc/themes/theme-4/covid-19>

If you want access to the information in your or your baby's medical records, then you should contact your NHS hospital or doctor.

What if I do not want to be involved?

Hospitals will record if patients do not want their medical records to be used for audit or research. You should tell your doctor or hospital if you do not want your records or those of your baby to be used in the study. If you choose to opt out, a small amount of your personal information (such as NHS number) will be held for the duration of the study, to make sure no further information is collected about you.

You can also let the study team know if you do not want your information and that of your baby to be used in this study by email: bpsu-covid@ndph.ox.ac.uk; by telephone: 01865 289733; or by writing to: BPSU COVID-19 Study, National Perinatal Epidemiology Unit, Nuffield Department of Population Health, Richard Doll Building, University of Oxford Old Road Campus, Old Road, Headington, Oxford OX3 7LF.

Who is funding and supporting this study?

The Department for Health is funding this study. Bliss, the newborn baby charity, are supporting the study (www.bliss.org.uk).

Where will the results be published?

Once the study is completed, you will be able to find the results on the study website: <https://www.npeu.ox.ac.uk/pru-mnhc/themes/theme-4/covid-19> and we will share the results widely with parents and groups representing them.

Who has reviewed this study?

The study was approved by North East –Newcastle & North Tyneside 2 Research Ethics Committee: REC 20/NE/0107, the Health Research Authority Confidentiality Advisory Group (England and Wales) and the Public Benefit and Privacy Panel (Scotland).

Who to contact if you have any questions

If you have questions please email: bpsu-covid@ndph.ox.ac.uk

or telephone: 01865 289733 the study team and we will get the best person to get in touch to answer your question.

What is the British Paediatric Surveillance Unit (BPSU)?

The aim of the BPSU is to encourage the study of rare conditions in children. It was founded in 1986 by the Royal College of Paediatrics and Child Health, Public Health England and Great Ormond Street Institute of Child Health (University College London).

What does the BPSU do?

It allows doctors and researchers to find out how many children in the UK and the Republic of Ireland are affected by a particular disease or condition each year - this is called surveillance. Doctors can also collect information about children with a particular rare condition. This will help them to understand what might have caused the condition and how to manage it better. BPSU studies can help future patients with a similar rare condition.

How does the BPSU work?

Each month the BPSU sends an online e-card to over 4,000 consultant paediatricians and specialist doctors. The card lists any rare conditions currently being studied. If any doctor has seen a child with one of these conditions they tick a box on the card and send it back. The BPSU tells the research team who send the doctor a short confidential questionnaire asking for more information from the medical record. Researchers are not told the names and addresses of patients, and families are not contacted.

What has the BPSU achieved?

The BPSU has now helped to undertake studies of over 120 rare conditions that affect children. These have helped to improve understanding of the rare conditions, such as why they occur and how to improve prevention, treatment and care.

For further information about the BPSU contact:

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