

# Neonatal complications of coronavirus disease (COVID-19) study

<b>Submission date</b> 30/07/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 31/07/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/11/2023	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Coronavirus disease (COVID-19) is an international public health crisis and is rapidly spreading around the world. So far it looks like most newborn babies and infants are not severely affected, but this is based on information about very small numbers of babies so there might be important effects of COVID-19 in babies that we don't yet know about.

There are three main ways that COVID-19 might affect newborns and babies that need hospital care when they are born or soon afterwards:

1. Newborn babies might catch COVID-19 before, during or soon after birth and this may lead to problems with breathing or feeding that need support in hospital.
2. COVID-19 could affect babies that are already on neonatal units with other medical conditions (like being very premature) that make them more at risk of severe infection.
3. COVID-19 might affect that way that pregnant women are looked after in pregnancy or labour which could lead to problems for some babies, even if they do not catch COVID-19

We plan to look at how COVID-19 is affecting newborns and babies who require hospital care in the United Kingdom (UK) through the British Paediatric Surveillance Unit (BPSU) notification system. To do this we will ask all paediatricians (doctors who look after babies and children) across the UK to report any baby they look after that is affected by COVID-19 as described above.

We will then ask the paediatricians looking after babies affected by COVID-19 some simple questions about how the baby is affected, what treatment they need, and what happens after the infection. We will use information that is routinely collected by doctors and nurses on neonatal units and paediatric intensive care units to better understand what medical treatments babies with COVID-19 receive. We will also link up with a similar surveillance study looking at COVID-19 in pregnant women (called UKOSS) and work with Public Health England (PHE) and similar organisations in Wales, Scotland and Northern Ireland to get a complete picture of the neonatal complications of COVID-19.

### Who can participate?

Babies diagnosed with COVID-19 (SARS-CoV-2 infection) or born to mothers with COVID-19 (SARS-CoV-2 infection).

### What does the study involve?

We will only collect information about the affected babies and this study will not affect the care that the babies receive.

The collection of information is from medical records only and does not require active participation by parents.

### What are the possible benefits and risks of participating?

This is an 'observational' study which involves the collection of information from medical records and will not affect the care that babies receive and it therefore does not involve any risks or benefits for the babies whose information is included.

### Where is the study run from?

The study is being run by a collaboration of researchers from across the UK and is being organised from the National Perinatal Epidemiology Unit (NPEU) in the Nuffield Department of Population Health at the University of Oxford.

### When is the study starting and how long is it expected to run for?

The study will collect information about eligible babies from 1st March 2020 to 31st March 2021. To ensure that we collect all the information require the study will continue until 30th September 2022.

### Who is funding the study?

The study is funded by a grant provided by the NIHR Policy Research Programme through the NIHR Policy Research Unit in Maternal and Neonatal Health and Care which is based at the NPEU, University of Oxford and with collaborators at the Universities of Leicester, Birmingham, Cardiff, and Manchester, Imperial College London and University College London (PR-PRU-1217-21202).

### Who is the main contact?

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## Contact information

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Scientific

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

282127

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

IRAS 282127

## **Study information**

**Scientific Title**

Neonatal complications of coronavirus disease (COVID-19) study

**Study objectives**

Coronavirus disease (COVID-19) is an international public health crisis and has rapidly spread around the world. Evidence to date suggests that most newborn babies and infants are not severely affected, but this is based on small numbers of cases so there might be important effects of COVID-19 in babies that we don't yet know about.

This observational study is designed to investigate the incidence, presentation, mode of transmission, severity, management and outcomes for hospitalised neonates diagnosed with SARS-CoV-2 before they are 29 days old; and the secondary impacts on babies born to mothers diagnosed with COVID-19 where the baby is admitted for hospital care.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 29/03/2020, North East - Newcastle & North Tyneside 2 Research Ethics Committee (NHS BT Blood Donor Centre, Holland Drive, Newcastle upon Tyne, Tyne and Wear NE2 4NQ, UK; +44 (0)207 972 2503; newcastlenorthtyneside2.rec@hra.nhs.uk), ref 20/NE/0107

### **Study design**

Observational national prospective cohort study

### **Primary study design**

Observational

### **Study type(s)**

Other

### **Health condition(s) or problem(s) studied**

COVID-19 (SARS-CoV-2 infection)

### **Interventions**

Observational study: using the British Paediatric Surveillance Unit system we will collect information about presentation, mode of transmission, severity, management and outcomes for hospitalised neonates diagnosed with SARS-CoV-2 and the same information for babies born to mothers with COVID-19 disease from 1st March 2020 until 31st March 2021.

### **Intervention Type**

Other

### **Primary outcome(s)**

Incidence of neonatal COVID-19 and mode of transmission measured using patient records from the British Paediatric Surveillance Unit system from 1st March 2020 until 31st March 2021

### **Key secondary outcome(s)**

Measured using patient records from the British Paediatric Surveillance Unit system from 1st March 2020 until 31st March 2021:

1. Presentation natural history and clinical presentation of neonatal hospitalised SARS-CoV-2
2. Presentation of neonates hospitalised whose mothers have COVID-19
3. Management, clinical treatment and outcomes of hospitalised neonates with SARS-CoV-2
4. Management, clinical treatment and outcomes of hospitalised neonates with SARS-CoV-2
5. Management, clinical treatment and outcomes of hospitalised neonates with SARS-CoV-2

## 6. Management, clinical treatment and outcomes of hospitalised neonates born to mothers with COVID-1

### Completion date

30/09/2022

## Eligibility

### Key inclusion criteria

Two groups of babies are eligible for inclusion:

1. Babies who have a diagnosis of SARS-CoV-2 infection made on a sample taken in the first 28 days and received inpatient care on a postnatal ward, neonatal unit, paediatric inpatient ward or paediatric intensive care unit
2. Babies born to mothers with COVID-19 where the baby requires hospital care within the first 28 days after birth

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Mixed

### Sex

All

### Total final enrolment

66

### Key exclusion criteria

Does not meet inclusion criteria

### Date of first enrolment

01/03/2020

### Date of final enrolment

30/03/2022

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

**University of Oxford**  
National Perinatal Epidemiology Unit  
Nuffield Department of Population Health  
Old Road Campus  
Headington  
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## Sponsor information

### Organisation

University of Oxford

### ROR

<https://ror.org/052gg0110>

## Funder(s)

### Funder type

Government

### Funder Name

National Institute for Health Research

### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

Individual participant data (IPD) sharing plan

Individual data will be shared with a global register of babies affected by COVID-19 and a prospective individual patient meta-analysis being carried out as a WHO collaboration.

## IPD sharing plan summary

Stored in repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Characteristics and outcomes of neonatal SARS-CoV-2 infection	01/02/2021	16/02/2021	Yes	No
<a href="#">Results article</a>	Neonatal outcomes of maternal SARS-CoV-2 infection	10/03/2023	13/03/2023	Yes	No
<a href="#">Results article</a>		15/11/2023	16/11/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol (other)</a>			13/03/2023	No	No
<a href="#">Protocol file</a>	version 2	11/05/2020	13/03/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes