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Neonatal complications of coronavirus disease (COVID-19) study

Submission date
30/07/2020

Recruitment status
No longer recruiting

Registration date
31/07/2020

Overall study status
Completed

Last Edited
16/11/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Backgroud 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 hosptial 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 thesefore 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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Study website
https://www.npeu.ox.ac.uk/pru-mnhc/research-themes/theme-4/covid-19

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
282127

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Epidemiological study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/03/2020

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

Age group
Mixed

Sex
Both

Target number of participants
As a national observational study we will include all eligible babies during the study period. The total number will not be known until we have finished recruiting.

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
England

United Kingdom

Study participating centre
University of Oxford
National Perinatal Epidemiology Unit
Nuffield Department of Population Health
Old Road Campus
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Sponsor information

Organisation
University of Oxford

Sponsor details
The University of Oxford, Clinical Trials and Research Governance Joint Research Office
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Sponsor type
University/education

Website
http://www.ox.ac.uk/

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

Publication and dissemination plan
We plan two publications in the first instance:
1. Analysis of the babies who have SARS-CoV-2 infection who were diagnosed in March and April 2020.
2. Analyis of both cohorts of babies, those with SARS-CoV-2 infection and those born to mothers with COVID-19 once the study has completed data collection.

Intention to publish date
30/03/2024

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

	Date	Date	Peer	Patient-

Output type	Details	created	added	reviewed?	facing?
Results article	Characteristics and outcomes of neonatal SARS-CoV-2 infection	01/02/2021	16/02/2021	Yes	No
Protocol (other)			13/03/2023	No	No
Protocol file	version 2	11/05/2020	13/03/2023	No	No
Results article	Neonatal outcomes of maternal SARS-CoV-2 infection	10/03/2023	13/03/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article		15/11/2023	16/11/2023	Yes	No