ISRCTN68026880 https://doi.org/10.1186/ISRCTN68026880

A global registry of women affected by COVID-19 in pregnancy and their babies, to guide treatment and prevention

Submission date
29/04/2020

Recruitment status
No longer recruiting

Registration date
30/04/2020

Overall study status
Completed

Last Edited
28/08/2024

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.
In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of April 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.
Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.
There is a need to rapidly collect and pool data on pregnant women affected by suspected or confirmed COVID-19 to inform treatment and preventative strategies in this and future outbreaks. The aim of this study is to create a global registry gathering data on the effect of SARS-CoV-2 infection in pregnancy from healthcare systems around the world. The researchers are endorsed by the International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) and the International Federation of Gynecology and Obstetrics (FIGO) who will support the study through their members and networks.

Who can participate?
Women aged 18-50 who are pregnant and their babies, with suspected or confirmed COVID-19

What does the study involve?
Data will be collected between January 2020 and March 2021 focusing on miscarriage, fetal growth restriction and stillbirth, pre-term delivery and potential transmission to the baby. The

study will also collect data on ultrasound diagnosis and neonatal care not included in other more general studies. Data entry can be performed by any healthcare professional in maternity services. The researchers will engage with obstetricians (Attendings/Consultants and those in training) and midwives to ensure data collection is as wide and full as possible. Investigators can register their interest to add data to the registry through the web page (https://pan-covid.org). Once registered they will be asked to provide confirmation of their local approval, which will allow data entry.

What are the possible benefits and risks of participating?
There are no direct benefits or risks of participation, the data gathered will be used to inform treatment and prevention of COVID-19.

Where is the study run from?
Imperial College Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
January 2020 to September 2021

Who is funding the study?
UK Research and Innovation

Who is the main contact?
Dr Edward Mullins
edward.mullins@imperial.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Edward Mullins

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)
282655

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
20QC5917, IRAS 282655

Study information

Scientific Title
Pregnancy and Neonatal Outcomes in COVID-19: a global registry of women with suspected COVID-19 or confirmed SARS-CoV-2 infection in pregnancy and their neonates; understanding natural history to guide treatment and prevention

Acronym
PAN-COVID

Study objectives
To understand the natural history of COVID-19 in pregnancy, in order to guide treatment and prevention during the outbreak.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/04/2020, North West - Haydock Research Ethics Committee (3rd Floor - Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048387 or +44 (0)2071048165; haydock.rec@hra.nhs.uk), ref: 20/NW/0212

Study design
Observational pregnancy register

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection) in pregnancy and neonates

Interventions
The study will form a global disease registry linked with other national data sources for women with suspected COVID-19 or confirmed SARS-CoV-2 in pregnancy and their neonates. Investigators can register their interest to add data to the registry through the web page (https://pan-covid.org). Once registered they will be asked to provide confirmation of their local

approval, which will allow data entry. Data will be collected from 01/01/2020 to 31/03/2021 on miscarriage, pre-term delivery, fetal growth restriction and neonatal outcomes, to assess the effect of a SARS-CoV-2 infection.

Intervention Type
Other

Primary outcome(s)
1. Confirmed SARS-CoV-2 infection in women in pregnancy or their neonates, measured using routine clinical data from 01/01/2020 to 31/03/2021
2. Suspected SARS-CoV-2 (defined as woman self-isolating for suspected COVID-19 with symptoms, symptoms will be recorded) measured using routine clinical data from 01/01/2020 to 31/03/2021

Key secondary outcome(s))
1. Incidence of miscarriage measured using routine clinical data from 01/01/2020 to 31/3/2021
2. Incidence of fetal growth restriction and stillbirth measured using routine clinical data from 01/01/2020 to 31/3/2021
3. Incidence of preterm birth measured using routine clinical data from 01/01/2020 to 31/3/2021
4. Incidence of vertical transmission to the neonate measured using routine clinical data from 01/01/2020 to 31/3/2021
5. Co-morbidities measured using routine clinical data from 01/01/2020 to 31/3/2021
6. Medical history measured using routine clinical data from 01/01/2020 to 31/3/2021
7. Details of the delivery of baby/babies measured using routine clinical data from 01/01/2020 to 31/3/2021

Completion date
30/09/2021

Eligibility

Key inclusion criteria
1. Women aged 18-50 who are pregnant and their babies
2. Suspected COVID-19 or confirmed SARs-CoV-2 infection
3. Delivery or pregnancy loss between January 2020 and March 2021

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
50 years

Sex
All

Total final enrolment
8239

Key exclusion criteria
Individuals who do not meet the inclusion criteria

Date of first enrolment
01/01/2020

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
United Kingdom

England

Argentina

Australia

Austria

Belgium

Bosnia and Herzegovina

Brazil

Canada

Chile

Colombia

Czech Republic

Ecuador

Egypt

Estonia

Germany

Greece

Guatemala

Hungary

India

Indonesia

Ireland

Israel

Italy

Japan

Latvia

Lebanon

Malta

Mexico

Netherlands

Nigeria

Peru

Portugal

Qatar

Romania

Russian Federation

South Africa

Spain

Thailand

Tunisia

Uganda

United Arab Emirates

United States of America

Study participating centre
Imperial College Healthcare NHS Trust
Du Cane Road
London
United Kingdom
W12 0HS

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Research organisation

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
CTR, Cardiff University is responsible for building, maintaining, cleaning and analysing the database. All enquiries should be directed to the PI, Edward Mullins (Edward.mullins@imperial.

ac.uk) or Julia Townson (townson@cardiff.ac.uk). The data will be available upon request and an agreed/signed data-sharing agreement. De-identified participant data will be made available to the scientific community with as few restrictions as feasible, whilst retaining exclusive use until the publication of major outputs. Cardiff University holds data for 15 years.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/07/2022	28/08/2024	Yes	No
Protocol article	protocol	29/01/2021	01/02/2021	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes