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UKOSS: Pandemic COVID-19 in pregnancy

Submission date
27/03/2020

Recruitment status
No longer recruiting

Registration date
01/04/2020

Overall study status
Completed

Last Edited
10/05/2024

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] 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 March 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 pregnant women. 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.
In 2012, a study was set up to investigate the effects of a pandemic (widespread infection across many regions of the world) of influenza (flu) on pregnant women and their babies. This study was not activated because an influenza pandemic did not happen in the period between 2012 and 2020. That study has now been adapted to investigate the effects of coronavirus infection and treatments on pregnant women and has been activated.

Who can participate?
All pregnant women aged 16-45 years who are admitted to one of the participating hospitals with coronavirus infection.

What does the study involve?
Participants will receive treatment and care as usual. The study will record what happens in terms of the pregnancy and the health of the mother and baby up until after the baby is born. No personal details will be recorded, so the participants will not be identifiable.

What are the possible benefits and risks of participating?
There are no benefits or risks to participants as they will receive the same treatment and care as if they had not participated in the study. The information collected will not be linked to any personal data, so participants will not be identifiable and will remain completely anonymous.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
January 2020 to March 2023

Who is funding the study?
The National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Professor Marian Knight

Study website
https://www.npeu.ox.ac.uk/ukoss

Contact information

Type(s)
Scientific

Contact name
Prof Marian Knight

ORCID ID
http://orcid.org/0000-0002-1984-4575

Contact details
National Perinatal Epidemiology Unit
Old Road Campus
University of Oxford
Oxford
United Kingdom
OX3 7LF
+44 (0)1865 289727
marian.knight@npeu.ox.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
112935

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
CPMS 14162, IRAS 112935

Study information

Scientific Title
Maternal and perinatal outcomes of pandemic COVID-19 in pregnancy

Study objectives
This NIHR-supported study is a national study of women hospitalised with confirmed COVID-19 in pregnancy. The study, funded by the NIHR, will use the UK Obstetric Surveillance System (UKOSS) to collect information about all pregnant women admitted to hospital who are confirmed to have coronavirus infection. The information will be analysed on a continuous basis to inform ongoing guidance for women and maternity staff as we respond to the pandemic. Specifically, the study will describe incidence, management and outcomes of COVID-19 in pregnancy and identify factors associated with better outcomes for women and their babies. Anonymous information will be collected through the existing UK Obstetric Surveillance System (UKOSS) reporters, who are based in all maternity units in the UK. Reporters have been sent a live link to allow them to notify cases and complete an anonymous data collection form.
This is an amendment to a study established in 2012 to learn more about the effects of a future worldwide influenza epidemic and its treatment on pregnant women and their babies using the UK Obstetric Surveillance System (UKOSS). That study was not activated.
Novel coronavirus is a new strain of coronavirus that has not previously been identified in humans. An outbreak of novel coronavirus was reported in Wuhan, China, in December 2019 with increasing global transmission. It is a respiratory illness, the symptoms of which usually include cough, high temperature and feeling short of breath, but it is not known what impact the virus will have on pregnant women and their babies. In order to investigate risk factors, management and outcomes, the researchers plan to extend data collection to include data on all pregnant women hospitalised with novel coronavirus should a pandemic be declared and hence the study activated by the NIHR.
The aim of this study is to learn more about the effects of a future worldwide flu or novel coronavirus epidemic and its treatment on pregnant women and their babies. Any new virus is different from previous viruses and this means that very few people have natural immunity or resistance to it. Because the virus is new, little is known about its effect. Certain groups of people, including pregnant women, are known to be at increased risk of developing more serious problems, as was shown in the 2009-2010 H1N1 'swine flu' epidemic.
In a future pandemic, however, these observed patterns may differ, and a rapid study of this susceptible group will be important to inform both ongoing preventative and management policies. This study aims to collect anonymous information about women who are admitted to hospital in the UK with confirmed novel coronavirus infection in pregnancy in the event of a future pandemic. This information will be collected through doctors and midwives in hospitals throughout the UK using an existing information collecting system, the UK Obstetric Surveillance System (UKOSS). By studying all the pregnant women admitted to hospital, the researchers hope to identify whether certain groups of pregnant women are more at risk of the more severe problems caused by pandemic novel coronavirus, and whether any particular additional treatment in pregnancy helps lessen these risks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Original pandemic influenza study (ISRCTN44137563) approved 11/09/2012, NRES Committee East Midlands - Nottingham 1 (The Old Chapel, Royal Standard Place, Nottingham NG1 6FS; +44 (0)115 883 9309; wendy.rees@nottspct.nhs.uk), ref: 12/EM/0365
2. Amendment enabling adaptation for COVID pandemic approved 09/03/2020, NRES Committee East Midlands - Nottingham 1 (The Old Chapel, Royal Standard Place, Nottingham NG1 6FS; +44 (0)207 104 8016; nrescommittee.EastMidlands-Nottingham1@nhs.net), ref: 12/EM/0365

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort 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) in pregnant women

Interventions
Research design:
This cohort study will use the UK Obstetric Surveillance System (UKOSS) to identify women hospitalized with pandemic novel coronavirus infection in pregnancy throughout a 6-month period. Participants will receive their usual management and information will be collected subsequently, detailing their treatment and outcomes. Research participants will not be contacted directly and no personally identifiable information (names, addresses or dates of birth will be collected.

Cohort identification:
Infected women will be identified through the UKOSS network of nominated reporting clinicians in each consultant-led maternity unit in the UK. Nominated reporting clinicians will be asked to report all pregnant women with confirmed pandemic novel coronavirus infection admitted to their unit. In view of the need for rapid and ongoing data analysis and production of guidance, we will use a specific web-based rapid reporting and data collection system for this study to enable UKOSS nominated clinicians to report cases as they occur. In addition, nominated clinicians will be sent a standard UKOSS reporting card each month to further enhance case ascertainment.

Comparison group identification:
Information about comparison women will be obtained from previously conducted UKOSS studies. Previous UKOSS studies have collected detailed demographic, pregnancy and delivery information about a cohort of over 1200 women giving birth in the UK identified from the same hospitals as infected women. This pragmatic approach has been adopted to allow risk factors for severe outcomes of pandemic influenza or novel coronavirus to be identified while minimizing the data collection burden on reporting clinicians during the pandemic.

Data gathering:
On receiving a case report, the central team will dispatch a data collection form to the clinician. The data collection form will seek confirmation of the appropriate case definition and additional information on risk factors, management and outcomes. Cases will be allocated central UKOSS identification numbers. No names, addresses, dates of birth, hospital or NHS numbers will be sought. respondents will be asked only to record the unique identification number in order to facilitate elimination of duplicate reports. If a completed data collection form is not received back by the central team after 3 weeks, a further form will be sent out. If there is still no response after a further 3 weeks, the clinicians will be contacted by telephone. If a data collection form is received back indicating that the women has not yet delivered, the clinician will be sent a second identical data collection form after the estimated date of delivery and asked to complete further details of delivery and outcomes.

Monitoring data collection & analyses:
The response rate from reporting clinicians will be monitored throughout the course of the study, as part of the routine operation of UKOSS. On a monthly basis throughout the study, incidence data with 95% confidence intervals will be calculated and outcomes of pregnancy explored.

Consultation:
The research design and protocol has been discussed by the Steering Committee of the UK Obstetric Surveillance System, which includes both lay and professional representatives.

Timetable - activation phase:
Week 1: Study information mailed/emailed to clinicians
Week 3: Data collection commenced
Months 2-6: Ongoing reporting of new cases, data analysis, production of management guidance and dissemination
Months 7-10: Collection of remaining pregnancy outcome data
Month 12: Final pregnancy outcome analysis, production of guidance and dissemination

Intervention Type
Mixed

Primary outcome measure
Incidence of pandemic COVID-19 in pregnancy assessed as proportion of pregnant women hospitalised with confirmed COVID-19 disease per 100,000 maternities during the study period

Secondary outcome measures
1. Maternal death assessed using medical records from entry into the study until 6 weeks after giving birth or the end of pregnancy
2. Other major complication (critical care unit admission, receipt of extracorporeal membrane oxygenation [ECMO], confirmed pneumonia on imaging) assessed using medical records from

entry into the study until death or hospital discharge
3. Perinatal death assessed using medical records as proportion of babies of pregnant women hospitalised with confirmed COVID-19 who were stillborn at 24 weeks or greater gestation, or who died in the first 7 days of life, per 1000 total births

Overall study start date
24/01/2020

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Any pregnant woman hospitalised who has tested positive for COVID-19 will be included.
2. Aged 16-45 years.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 500; UK Sample Size: 500

Total final enrolment
427

Key exclusion criteria
1. Any woman not meeting the criteria.

Date of first enrolment
20/03/2020

Date of final enrolment
20/03/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
National Perinatal Epidemiology Unit
Nuffield Department of Population Health
University of Oxford
Old Rd Campus
Oxford
United Kingdom
OX3 7LF

Sponsor information

Organisation
University of Oxford

Sponsor details
Clinical Trials & Research Governance
Joint Research Office
Boundary Brook House
Churchill Drive
Oxford
United Kingdom
OX3 7GB
+44 (0)1865 572224
heather.house@admin.ox.ac.uk

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
Not provided at time of registration.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be shared according to the NPEU data sharing policy https://www.npeu.ox.ac.uk/downloads/files/npeu/policies/Data%20Sharing%20Policy.pdf.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/06/2020	10/06/2020	Yes	No
Preprint results	Impact of SARS-CoV-2 variant	25/07/2021	31/08/2021	No	No
Interim results article	comparison between outcomes collected in the periods in which wildtype, alpha variant, and delta variant of SARS-CoV-2 were dominant in the UK	19/01/2022	09/03/2022	Yes	No
Interim results article	population level data on risk factors, incidence and impact of SARS-CoV-2 infection in pregnant women	05/05/2021	09/03/2022	Yes	No
Interim results article	secondary analysis of data	25/02/2022	09/03/2022	Yes	No
Results article		24/08/2022	21/03/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article		15/04/2024	10/05/2024	Yes	No