ISRCTN11681816 https://doi.org/10.1186/ISRCTN11681816

Effects of the amount of SARS-CoV-2 in the maternal airways on outcomes before, during, and after childbirth

Submission date
31/10/2021

Recruitment status
No longer recruiting

Registration date
08/11/2021

Overall study status
Completed

Last Edited
20/12/2023

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection has interested a relevant number of pregnant women worldwide with negative consequences both on the maternal and neonatal side. For instance, COVID-19 is more severe in pregnant women, preterm delivery is more common and neonates have a higher chance to need intensive care admission. Finally, SARS-CoV-2 mother-to-child transmission is possible and neonatal COVID-19 can be observed although rarely. Despite the viral load has been linked to the clinical severity of COVID-19 in non-pregnant patients, the relationship between SARS-CoV-2 viral load and perinatal outcomes in pregnant women affected by COVID-19 in late pregnancy is unknown. We sought to investigate whether or not nasopharyngeal SARS-CoV-2 viral load has any effect on perinatal outcomes, when COVID-19 is diagnosed in the third trimester of pregnancy.

Who can participate?
All women affected by COVID-19 during the third trimester of pregnancy (and not meeting exclusion criteria) were eligible.

What does the study involve?
Patient records from the start of the pandemic to mid-2021 will be analysed.

What are the possible benefits and risks of participating?
The study is retrospective, does not modify the routine care in any way and does not carry any risk for the patients.

Where is the study run from?
Hôpital “A. Béclère” (France)
The study is conducted in four academic tertiary referral perinatal center in major EU and UK cities. These centers have been chosen through contacts between peers for the availability of electronic databases of pregnant women affected by COVID-19 and their expertise on perinatal COVID-19 research.

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

Who is funding the study?
The study has no sponsor of any type and no honorarium is previewed for the participation to the study. Authors are performing the study for free during their worktime and they do not have any conflict of interest to disclose in relation to the project.

Who is the main contact?
Prof. Daniele De Luca, dm.deluca@icloud.com

Contact information

Type(s)
Scientific

Contact name
Prof Daniele De Luca

ORCID ID
http://orcid.org/0000-0002-3846-4834

Contact details
Service de Pédiatrie et Réanimation Néonatale,
Hôpital “A. Béclère”, GHU Paris Saclay - APHP
157 rue de la Porte de Trivaux
Clamart
France
92140
+33 (0)145374837
DANIELE.DELUCA@APHP.FR

Type(s)
Public

Contact name
Prof Daniele De Luca

Contact details
Service de Pédiatrie et Réanimation Néonatale,
Hôpital “A. Béclère”, GHU Paris Saclay - APHP
157 rue de la Porte de Trivaux
Clamart
France
92140
+33 (0)145374837
dm.deluca@icloud.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effect of SARS-CoV-2 estimated nasopharyngeal viral load on perinatal outcomes in pregnant women affected by COVID-19 during the third trimester (VALOROUS study)

Acronym
VALOROUS

Study objectives
To verify if maternal viral load in the airways is associated with perinatal outcomes in women affected by COVID-19 in the third trimester of pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/11/2020, Ethical committee of the Department of Women and Newborn Health (Paris Saclay University Hospitals, APHP, Paris, France; +33 0492034409; cppsudmediterraneeV@chu-nice.fr), ref: CPP Sud Méditerranee n.2020-A00924-35

Study design
Multicenter international observational retrospective 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 to request a patient information sheet.

Health condition(s) or problem(s) studied
Effect of SARS-CoV-2 estimated nasopharyngeal viral load on perinatal outcomes in pregnant women affected by COVID-19 during the third trimester

Interventions
Nasopharyngeal swabs will be obtained following US Center for Disease Control and Prevention guidelines. Extraction and amplification will be performed with commercial assays validated for SARS-CoV-2 diagnosis by WHO or local healthcare authorities. Manufacturer's recommendations will always be followed. The SARS-CoV-2 load will be estimated for any viral gene, according to each laboratory protocol. RT-PCR technique will be performed according to European Center for Disease Prevention and Control.

The following data will be collected: basic maternal and neonatal demographics, birth weight Z-score, time between COVID-19 diagnosis and delivery, 5' Apgar score, cord pH, estimated viral load for any vital gene, COVID-19 severity. These variables were chosen in order to keep a pragmatic design and make from the different centers easy to merge.

Data will be collected retrospectively to the start of the pandemic and prospectively to the end of the study.

Intervention Type
Other

Primary outcome measure
1. Estimated viral load measured at birth using the number of cycles at the RT-PCR on maternal nasopharyngeal swab according to best microbiological practice
2. Gestational age at the birth measured using patient records
3. Birth weight and its Z-score measured using patient records
4. 5'Apgar score measured at birth by adequately trained midwives or neonatologists
5. Cord pH measured at birth using potentiometric point of care method on cord arterial puncture

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/03/2020

Completion date
31/08/2021

Eligibility

Key inclusion criteria
1. Third trimester of pregnancy
2. Diagnosis of COVID performed according to World Health Organization criteria
3. Viral load estimated by real-time polymerase chain reaction cycle threshold (Ct) for any viral gene

Participant type(s)

Patient

Age group
Adult

Sex
Female

Target number of participants
100

Total final enrolment
393

Key exclusion criteria
1. Fetal congenital malformations
2. Major genetic or chromosomal abnormalities
3. Ongoing pregnancies at the time of the analysis
4. Missing viral load or outcome data

Date of first enrolment
01/03/2020

Date of final enrolment
31/08/2021

Locations

Countries of recruitment
Belgium

England

France

Italy

United Kingdom

Study participating centre
Department of Women and Newborn Health, Medical Center A. Béclère, Paris Saclay University Hospitals, APHP
157, Rue de la porte de Trivaux
Clamart
France
92140

Study participating centre
Fetal Medicine Unit, Saint George's Hospital
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre
Department of Translational Medical Sciences, University of Naples Federico II
5, Via Sergio Pansini
Naples
Italy
80131

Study participating centre
Department of Obstetrics and Gynecology, Brugmann University Hospital, Université Libre de Bruxelles
4, Place A. Van Gehuchten
Brussels
Belgium
1020

Sponsor information

Organisation
Hôpital Antoine-Béclère

Sponsor details
DMU Santé Femme et Nouveau-né - Hopital "A.Béclère" - APHP
157 rue de la Porte de Trivaux
Clamart
France
92140
+33 (0) 1 45 37 44 76
alexandra.benachi@aphp.fr

Sponsor type
Hospital/treatment centre

Website
http://www.aphp.fr/contenu/hopital-antoine-beclere-1

ROR

https://ror.org/04sb8a726

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. Presentation in main international congresses in the field of ObGyn and Neonatology

Intention to publish date
01/02/2022

Individual participant data (IPD) sharing plan
Anonymous raw data will be available on reasonable request.
Data can be asked to investigators in each of the participating centers (for the data contributed by each center). Data will be totally anonymous. A restricted duration of availability and other restrictions may apply according to local regulations enforced in each center.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			02/11/2021	No	No
Results article		05/03/2023	20/12/2023	Yes	No