Severe COVID-19 In Pregnancy (SCIP): a pilot study
Linking disease severity to the maternal immune composition

Published: 07-09-2020
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To identify differences in immune cell repertoire between pregnant women with critical COVID-19, mild COVID-19 and healthy controls.

Ethical review	Approved WMO
Status	Pending
Health condition type	Immunodeficiency syndromes
Study type	Observational invasive

Summary

ID

NL-OMON49779

Source
ToetsingOnline

Brief title
SCIP pilot study

Condition

- Immunodeficiency syndromes
- Maternal complications of pregnancy
- Respiratory tract infections

Synonym
Corona virus, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: COVID-19, Immunology, Pregnancy

Outcome measures

Primary outcome

Immune composition(B cell and plasma cell subsets, small clonal B cell

populations, innate cells, T cell subsets, cytokine profile; using the EuroFlow

panel and Luminex assay)

Secondary outcome

NA

Study description

Background summary

Data on SARS-CoV-2 infection in pregnant women are limited. Based on current publications, the majority of pregnant women appears to have only mild symptoms of COVID-19, but a small part develops severe symptoms and needs hospital or Intensive Care Unit (ICU) admission. This particular group of patients may have an insufficiency in their immune repertoire. Previous observations suggested that abnormalities in the B cell compartment may predispose to an insufficiency in the immunity to SARS-CoV-2.

Study objective

To identify differences in immune cell repertoire between pregnant women with critical COVID-19, mild COVID-19 and healthy controls.

Study design

An observational single-centre case-control pilot study

Study burden and risks

Participating in this study will not yield direct benefits for the subjects. However, it may be valuable for future patients by leading to new insights and research directions for COVID-19. No additional risks or burden are expected from the study (except for the negligible risks associated with a one-time blood collection). If possible, blood collection may also be arranged at home. Participation does not influence standard care procedures.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Three groups of women will be eligible for inclusion in this pilot study:

1. COVID-19 during pregnancy: severe or critical disease
2. COVID-19 during pregnancy: mild disease
3. Healthy pregnant controls
4. COVID-19: non-pregnant women (from BEAT-COVID-1 study)

Mild, severe and critical disease are classified using the definitions of the WHO (WHO: Clinical management of severe acute respiratory infection when COVID-19 is suspected, March 13, 2020):
-mild disease: hospital interventions is not required, only symptomatic treatment (such as antipyretics for fever) and monitoring
-severe disease: hospitalization and oxygen therapy is required
-critical disease: acute respiratory distress syndrome (ARDS), advanced oxygen/ventilatory support is required

Inclusion criteria group 1
- Laboratory confirmation of SARS-CoV-2 infection
- Severe or critical disease

Group 2:
- Laboratory confirmation of SARS-CoV-2 infection
- Mild disease
- Similar maternal age and gestational age as one of the patients in group 1 (matched as accurately as possible)

Group 3:
- Similar maternal age and gestational age as one of the patients in group 1 (matched as accurately as possible)

Exclusion criteria

NA

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2020
Enrollment:	8
Type:	Anticipated

Ethics review

Approved WMO

Date:	07-09-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL74030.058.20