PREGCOVAC-19: the follow up of pregnant women who received COVID-19 vaccination in the Dutch national vaccination program

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We have defined the following milestones/deliverables for this project:1. Evaluation of IgG antibody response in pregnant women after participation in the Dutch national COVID-19 vaccination program.2. Evaluation of the relation between gestational...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON51101

Source
ToetsingOnline

Brief title
PREGCOVAC-19

Condition

- Viral infectious disorders
- Pregnancy, labour, delivery and postpartum conditions

Synonym
COVID-19 Vaccine, SARS-COV-2

Research involving
Human

Sponsors and support

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

Intervention

Keyword: COVID-19, Pregnancy, Vaccination

Outcome measures

Primary outcome

The description of the antibody response in maternal blood during pregnancy and the number of placental antibodies transferred as determined in umbilical cord blood in relation to the gestational age at vaccination..

Secondary outcome

- The number of neonates with an antibody response as reflected by IgG response in cord blood in relation to the gestational age at vaccination will be analyzed using lineair regression.

- The obstetric outcome in relation to the trimester in which vaccination was performed.

Study description

Background summary

Thus far over 64 million people have been infected with the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) worldwide with over 3 million global deaths, but understanding the effect of SARS-CoV-2 on pregnant women is still incomplete. Although severe COVID-19 illness is uncommon, pregnant women are more likely to require intensive care unit stay than same aged nonpregnant women, predominantly in the third trimester when the diaphragm is moved up from its prepregnancy position (2). Most effective novel drugs are contraindicated for pregnant women, considering scarcity of studies on safety data. These factors suggest that pregnant women are important candidates for preventive

measures, of which vaccination is gold standard (3). Pregnancy is an immunotolerant state and therefore the immune responses to vaccination in pregnant women cannot be assumed from that of nonpregnant women. Knowledge on the immune response after COVID vaccination in pregnant women is an urgent matter. From other widely used vaccinations in pregnancy, such as influenza and pertussis, the goal of vaccination in pregnancy is twofold: To protect both pregnant women and their offspring, for which antibody response and transplacental antibody transfer are prerequisite. Thus far it is unknown which trimester of pregnancy offers the best vaccine efficacy in terms of maternal protection by antibody response and fetal protection by antibody transfer. This is an important knowledge gap, as recent CDC data indicate that infants aged 0 to 2 months comprise 20% of all COVID-19 hospitalizations among children below 18 years (4). Initially the Dutch society of Obstetrics and Gynecology (NVOG) advised to vaccinate pregnant women with occupational SARS-CoV-2 exposure and women at increased risk for severe or critical COVID-19 only. As of April 22 2021, the NVOG changed this advice and currently advocates to vaccinate all pregnant women. (Update standpunt *Vaccinatie tegen COVID-19 rondom zwangerschap en kraambed* | NVOG)

Study objective

We have defined the following milestones/deliverables for this project:
1. Evaluation of IgG antibody response in pregnant women after participation in the Dutch national COVID-19 vaccination program.
2. Evaluation of the relation between gestational age at vaccination and maternal antibody response and trans placental IgG antibody transfer.
3. Registration of obstetric outcomes.

Study design

A prospective observational longitudinal cohort study with minimal invasive blood sampling:
1. Before vaccination
2. Fifteen days after the first and the second vaccination (if applicable in the Dutch national COVID-19 vaccination program)
3. At birth. Also cord blood will be collected and the obstetric outcome will be registered.
In total, a maximum of 10 ml blood at four time points and a maximum of 10 ml of cord blood will be collected.

Study burden and risks

It concerns a study with pregnant volunteers who have decided to get vaccinated through the Dutch national COVID-19 vaccination program. The study concerns the collection of blood and the filling out of questionnaires. There are no

associated risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Pregnant women (18 >= years) scheduled for COVID-19 vaccination

Exclusion criteria

-No written informed consent
-Age < 18 years
-No knowledge of Dutch or English language

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-06-2021
Enrollment:	250
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	COVID-19-vaccin (ChAdOx1-S [recombinant])
Product type:	Medicine
Brand name:	COVID-19 mRNA vaccine (nucleoside-modified)
Product type:	Medicine
Brand name:	COVID-19-vaccin (Ad26.COV2-S [recombinant])

Ethics review

Approved WMO

Date:	17-05-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	26-05-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2021-002327-38-NL
CCMO	NL77670.029.21