Immunity against SARS-Coronavirus-2 in breastmilk

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To evaluate the prevalence of SARS-CoV2 antibodies in breast milk of lactating mothers recovering from a proven or suspected SARS-CoV2 infection.Secundary: to evaluate the effect of the corona-pandemic on pyschological en biological stress in...

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

Summary

ID

NL-OMON54955

Source
ToetsingOnline

Brief title
COVID MILK - POWER MILK Study

Condition

- Viral infectious disorders

Synonym
Coronavirus, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Stichting Steun Emma (vierde geldstroom)

Intervention

Keyword: Antibodies, Breastmilk, Coronavirus, COVID-19

Outcome measures

Primary outcome

IgG and IgA against SARS-CoV2 will be determined in the collected blood samples.

Secretory IgA will be assessed in breast milk samples.

Cortisol in hair will be measured

Secondary outcome

All the data out of the questionnaire about general health, physical activity,

COVID-19 symptomens, diet, perceived stress.

Study description

Background summary

Coronavirus disease 2019 (COVID-19) first started in China in December 2019 and the outbreak was declared a pandemic by the World Health Organization (WHO) on 11 March 2020. There are vulnerable populations suffering severely from COVID-19 and some need to be hospitalized. Until now, there is no effective treatment or vaccine available. In general, maternal milk antibodies may provide additional protection to infants. Unpublished data from our recent study showed the presence of SARS-CoV2 antibodies in breastmilk in previously infected or suspected subjects, before and after pasteurization of the milk. However, this was tested in a small group of women and to be able to implement the antibody containing breastmilk into clinical practice we need to evaluate the prevalence of SARS-CoV2 antibodies in breastmilk in a larger population. In addition we want to study the amount of stress the pandemic has caused on this specific population that underwent a life event during this pandemic and its influence on the composition of milk. Moreover, we will evaluate the effect of vaccination on antibodies.

Study objective

To evaluate the prevalence of SARS-CoV2 antibodies in breast milk of lactating mothers recovering from a proven or suspected SARS-CoV2 infection.

Secundary: to evaluate the effect of the corona-pandemic on pyschological en biological stress in lactating women and the effect on antibody levels in breast milk.

To evaluate the effect of vaccination on the SARS-CoV-2 antibodies in breast milk and to evaluate the evolution of the antibodies following the first and second dose of the vaccine.

Study design

The study will be a prospective observational cohort study in which all participants will undergo blood sampling for circulating antibody analyses (specific IgG and IgA against SARS-CoV2) and breast milk sampling for antibody analysis (IgA against SARS-CoV2). Also, for this study a small strand of hair will be collected for cortisol analysis.
In addition, all participants will receive a questionnaire with questions regarding their general health and characteristics, diet, perceived stress, physical
activity, pregnancy and COVID-19 symptoms.

The vaccination follow-up study is a longitidinal study in which several blood and milk samples will be collected to evaluate the effect of vaccination on the antibodies.

Study burden and risks

We expect a low burden and low risk for the participating women. Participants can choose if they want to come to the Amsterdam UMC for the collection of body materials or that they would rather want the investigators to plan a home visit so that they don't have to travel. The only risks are pain and bleeding due to the vena puncture.

For the follow-up study, the risk is low.

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

- Lactating women
- For the follow-up study: participants who recieve a COVID-19 vaccination

Exclusion criteria

• No written informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2020
Enrollment:	5000
Type:	Actual

Ethics review

Approved WMO Date:	22-09-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-01-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-01-2021
Application type:	Amendment
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
CCMO	NL74752.029.20