Immunity against SARS-Coronavirus 2 in breast milk

Published: 17-04-2020
Last updated: 17-01-2025

1. To evaluate if breastmilk of mothers who recovered from a proven COVID-19 infection contains antibodies (IgA) against SARS-CoV2.2. To evaluate if these antibodies are still present after pasteurization according the Holder method.

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

Summary

ID

NL-OMON49658

Source
ToetsingOnline

Brief title
COVID MILK

Condition

- Viral infectious disorders

Synonym
Corona virus, 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, COVID-19, immunity

Outcome measures

Primary outcome

Neutralizing antibodies, IgG, IgA and IgM against SARS-CoV2 will be determined in the collected blood samples. Secretory IgA will be assessed in breast milk samples before and after Holder pasteurization.

Secondary outcome

not applicable

Study description

Background summary

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) is a positive-sense single-stranded RNA virus from the Coronaviridae family that is the cause of coronavirus disease 2019 (COVID-19). The virus was first identified in China in December 2019 and the outbreak was declared a pandemic by the World Health Organization (WHO) on 11 March 2020.
At this moment, there are some reports of COVID-19 in infants. Evidence is emerging that children suffer less severely from COVID-19, however, they do get infected and spread the virus.In addition, there are some neonates and infants suffering severely from COVID-19 and 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. It is known that antibodies against influenza are secreted into breast milk (and in lesser amounts available in donor breast milk) and that they may provide additional protection to young infants. However, there is not much known about transmission of antibodies to coronaviruses into human milk. During the SARS in 2002-2004 outbreak, a pregnant woman who got infected at the second trimester and required mechanical ventilation at the intensive care recovered and delivered a healthy 38-week infant. After birth, antibodies to SARS-CoV were detected in maternal serum, cord blood and milk with no evidence of the virus. So, there is some evidence that antibodies to coronaviruses are secreted in the breast milk. For SARS-CoV2 infection, this data is missing.
When a mother has been infected with a virus, antibodies are produced against

many epitopes on multiple virus proteins. A subset of these antibodies can block virus infection by a process that is called neutralization. Viruses, (such as SARS-CoV2) that infect mucosal surfaces could encounter secretory IgA antibodies present at the apical surfaces of epithelial cells. Viruses that spread in the blood will be exposed to IgG, IgA and IgM antibodies directed against this specific virus. Our aim is to measure the specific antibodies against SARS-COV 2 in breast milk. If these antibodies are present in breast milk, even after pasteurization, donor breast milk might be used to support young infants with a severe COVID-19 infection that need to be hospitalized. At this moment, there is no evidence that the virus is secreted by the mother*s milk and COVID-19 positive mothers are encouraged to maintain breast feeding after practice hand hygiene with a face mask, or by pumping their milk.

Study objective

1. To evaluate if breastmilk of mothers who recovered from a proven COVID-19 infection contains antibodies (IgA) against SARS-CoV2.
2. To evaluate if these antibodies are still present after pasteurization according the Holder method.

Study design

A prospective observational cohort study in which all participants will undergo blood sampling for circulating antibody analyses (neutralizing antibodies, specific IgG, IgA and IgM against SARS-CoV2) and breast milk sampling for circulating antibody analysis (IgA against SARS-CoV2). For this study 5 ml of blood will be collected and one portion of breast milk. The breast milk will be divided into two samples. One sample will be analysed directly and the other sample will be pasteurized first (Holder pasteurization: 30 minutes at 62,50 C), to examine the effects of pasteurization.

In addition, the following patient characteristics will be collected: age, days since recovery of clinical symptoms (fever > 37,5 C, cough, tachypnea, dyspnea, abdominal cramps, diarrhoea, headache, sore throat), days after giving birth, SARS-CoV2 PCR test results if available.

Study burden and risks

We expect a low burden and risk from our study. Participants don't have to come to the hospital. The only risks are pain and bleeding due to the vena puncture.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Lactating mothers with a proven COVID-19 infection

Exclusion criteria

No infection

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	24-04-2020
Enrollment:	55
Type:	Actual

Ethics review

Approved WMO Date:	17-04-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-05-2020
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	NL73686.029.20

Study results

Date completed: 31-07-2020

Results posted: 14-01-2021

First publication
14-01-2021