Assessment of Neonatal Cord Blood SARS-CoV-2 Antibodies after COVID-19 Vaccination in Pregnancy: A Prospective Cohort Study

Evaluation von SARS-CoV-2-Antikörpern im Nabelschnurblut von Neugeborenen nach COVID-19-Impfung während der Schwangerschaft: eine prospektive Kohortenstudie

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Schlüsselwörter

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ABSTRACT

Introduction Maternally derived antibodies are a key element of neonatal immunity. So far, limited data has shown transplacental transmission of antibodies after coronavirus disease 2019 (COVID-19) vaccination with BNT162b2 in the third trimester. Our aim was to detect vertically transferred immunity after COVID-19 vaccination with BNT162b2 (Comirnaty, BioNTech-Pfizer) or mRNA-1273 (Spikevax, Moderna) in the first, second or third trimester of pregnancy, and investigate the impact of maternal characteristics on umbilical cord antibody titre in newborns after delivery.

Study Design Women who gave birth in our department and were vaccinated against COVID-19 during pregnancy were enrolled in CRONOS Satellite, a subproject of the German COVID-19-Related Obstetric and Neonatal Outcome Study. The titre of immunoglobulin G (IgG) antibodies to the receptor-binding domain of the SARS-CoV-2 spike protein was quantified in umbilical cord blood using the SARS-CoV-2 IgG II Quant immunoassay. Correlations between antibody titre and variables, including week of pregnancy when vaccinated, interval between vaccination and delivery, age and body mass index (BMI) were assessed with Spearman's rank correlation. A follow-up was conducted by phone interview 4–6 weeks after delivery.

Results The study cohort consisted of 70 women and their 74 newborns. Vaccine-generated antibodies were present in all samples, irrespective of the vaccination type or time of vaccination. None of the parameters of interest showed a meaningful correlation with cord blood antibody concentrations (rho values < 0.5). No adverse outcomes (including foetal malformation) were reported, even after vaccination in the first trimester.

Conclusions Transplacental passage of SARS-CoV-2 antibodies from mother to child was demonstrated in all cases in the present study. It can therefore be assumed that the newborns of mothers vaccinated at any time during pregnancy receive antibodies via the placenta which potentially provide them

with protection against COVID-19. This is an additional argument when counselling pregnant women about vaccination in pregnancy.

ZUSAMMENFASSUNG

Einleitung Antikörper, die von der Mutter auf das Kind übertragen werden, sind ein Kernstück der neonatalen Immunität. Bislang gibt es nur wenige Daten, die auf eine diaplazentare Übertragung von durch die Coronavirus-Erkrankung-2019-(COVID-19-)Impfung mit BNT162b2 im 3. Trimenon generierten Antikörpern hinweisen. Ziel unserer Studie war es, die vertikal übertragene Immunität nach der COVID-19-Impfung mit BNT162b2 (Comirnaty, BioNTech-Pfizer) oder mRNA-1273 (Spikevax, Moderna) im 1., 2. oder 3. Trimenon zu ermitteln und die Auswirkungen von mütterlichen Charakteristika auf den Antikörpertiter im Nabelschnurblut von Neugeborenen nach der Geburt zu untersuchen.

Studiendesign Frauen, die in unserer Abteilung entbanden und während ihrer Schwangerschaft gegen COVID-19 geimpft wurden, wurden in CRONOS Satellite, ein Unterprojekt der deutschen COVID-19-Related-Obstetric-and-Neonatal-Outcome-Studie, aufgenommen. Der Titer von Immunglobulin-G-(IgG-)Antikörpern zur rezeptorbindenden Domäne des SARS-CoV-2-Spike-Proteins wurde mithilfe des SARS-CoV-2 IgG II Quant Immunoassays im Nabelschnurblut quantifiziert. Korrelationen zwischen Antikörpertiter und verschiedenen Variablen, darunter die Schwangerschaftswoche zum Zeitpunkt der Impfung, die Zeitspanne zwischen Impfung und Entbindung, das mütterliche Alter und der Body-Mass-Index (BMI), wurden mithilfe der Spearman-Korrelation evaluiert. Eine Nachbeobachtung wurde 4–6 Wochen nach der Entbindung per Telefoninterview durchgeführt.

Ergebnisse Die Studienkohorte bestand aus 70 Frauen und ihren 74 neugeborenen Kindern. Die durch die Impfung hervorgerufenen Antikörper fanden sich in allen Blutproben, unabhängig vom Impftypus oder Zeitpunkt der Impfung. Keiner der untersuchten Parameter wies eine aussagekräftige Korrelation mit den Antikörper-Konzentrationen im Nabelschnurblut auf (Rho-Werte < 0,5). Es gab keine unerwünschte Ereignisse (auch keine fötale Fehlbildungen), selbst nach einer Impfung im 1. Trimenon.

Schlussfolgerungen Eine diaplazentare Transmission von SARS-CoV-2-Antikörpern von Mutter zum Kind wurde in dieser Studie in allen Fällen festgestellt. Es kann daher angenommen werden, dass neugeborene Kinder von Müttern, die irgendwann während ihrer Schwangerschaft geimpft wurden, Antikörper durch die Plazenta erhalten, die den Kindern potenziell einen Schutz gegen COVID-19 bieten. Das ist ein weiteres Argument, das während der Beratung von schwangeren Frauen zur Impfung während der Schwangerschaft angeführt werden sollte.

Abbreviations

BMI	body mass index
CDC	Centres for Disease Control and Prevention
COVID-19	coronavirus disease 2019
CRONOS study	COVID-19-Related Obstetric and Neonatal Outcome Study
IgG	immunoglobulin G
IQR	interquartile range
mRNA	messenger RNA
SARS-CoV-2	severe acute respiratory syndrome coronavirus type 2
SPSS	Statistical Package for the Social Sciences

Introduction

The COVID-19 pandemic which emerged at the end of 2019 is still ongoing [1]. Due to mechanical, physiological, and immunologic changes, pregnant women are considered a vulnerable group and the risk of certain infections increases with pregnancy [2]. Although pregnancy does not increase the risk of acquiring SARS-CoV-2 infection, it appears to worsen the clinical course of SARS-CoV-2 infection compared with non-pregnant women of the same age [3]. Due to this circumstance, many international health organisations and professional societies recommend vaccination during pregnancy, including the Center for Disease Control and Prevention (CDC) of the United States, the American College of Obstetricians and Gynecologists, the German Society of Gynaecology and Obstetrics (DGGG), the German Society for Perinatal Medicine (DGPM) and the Standing Committee on Vaccination at the Robert Koch Institute (STIKO) [4 – 7].

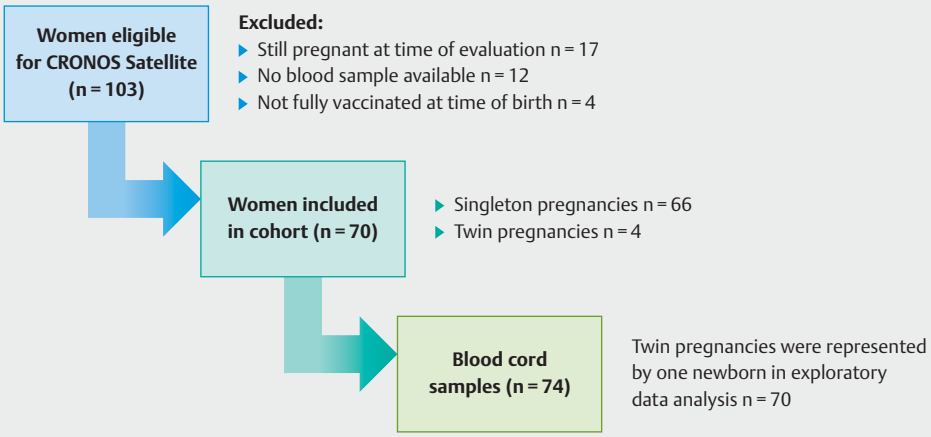
Newborn protection from infectious diseases is primarily dependent on innate neonatal immune responses and maternally derived, transplacentally acquired antibodies. Recent studies have demonstrated the presence of SARS-CoV-2 antibodies in cord blood after maternal SARS-CoV-2 infection; however, studies on antibody concentrations after vaccination have been limited to small sample sizes or to vaccination in the third trimester [8 – 14].

The concentration of maternally derived SARS-CoV-2 antibodies at birth is likely to be an important factor in protecting the newborn against COVID-19. Yet, the optimal time to vaccinate during pregnancy in order to achieve high antibody levels in the newborn is not known. This information can be important for counselling pregnant women and is a convincing argument for vaccination and/or booster vaccination during pregnancy.

We aimed to estimate vertically transmitted immunity after COVID-19 vaccination with BNT162b2 (Comirnaty, BioNTech, Pfizer) or mRNA-1273 (Spikevax, Moderna) during all trimesters of pregnancy and to investigate the influence of maternal characteristics on antibody titres in the umbilical cord at birth.

Methods

This prospective single centre study was designed in compliance with the Declaration of Helsinki and in accordance with the institutional review board. The study was approved by the ethics com-



▶ **Fig. 1** Flow diagram describing patient inclusion.

mittee of the medical association of Westfalen-Lippe and the Westphalian Wilhelms University of Münster (WWU), reference number: 2020-292-b-S. Written informed consent was obtained prior to enrolment.

Recruitment and inclusion criteria

Women giving birth between March 2021 and November 2021 at the University Hospital of Münster who were vaccinated against SARS-CoV-2 during pregnancy had the option to participate in the CRONOS Satellite, a subproject of the German Covid-19-Related Obstetric and Neonatal Outcome Study (CRONOS) [15]. The primary aim of the prospective CRONOS registry is to research the effects of an infection with the novel coronavirus SARS-CoV-2 or the effects of vaccination against SARS-CoV-2 in pregnancy (CRONOS Satellite) on the health of mother and neonate.

In the subgroup who delivered at our hospital, we additionally assessed neonatal antibody status from umbilical blood samples in a cohort of double-vaccinated women who participated in CRONOS Satellite and had singleton or twin live births. Written consent was obtained during pregnancy and umbilical venous blood samples were examined directly after delivery. The titre of IgG to the receptor-binding domain of the SARS-CoV-2 spike protein was measured using the chemiluminescent microparticle SARS-CoV-2 IgG II Quant immunoassay (Abbott Diagnostics, Germany).

Data collection

Data were collected from internal electronic medical records and a specifically developed electronic case report file at CASTOR EDC (castoredc.com, Amsterdam, NL) [15]. These contained the full medical history of the mother (BMI, smoking status, gravidity, parity, concomitant diseases), demographic characteristics (ethnicity, age), gestational week at the time of delivery and vaccination history, including pregnancy week at the time of first and second vaccination, type of vaccine, reason for vaccination, and symptoms after vaccination. A follow-up with a structured phone interview 4–6 weeks after delivery collected data on maternal and neonatal well-being, adverse outcomes or child malformation.

Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) software, version 28 (IBM Corporation, New York, NY, USA). Descriptive statistics were used to characterise the study population. Normally and non-normally distributed parameters are shown as median and interquartile range. All examined parameters except maternal age were non-normally distributed and were analysed as such. All inferential statistics are intended to be exploratory (hypothesis generating), not confirmatory, and are interpreted accordingly. Therefore, no power calculation was performed. The p-values are considered significant if $p \leq 0.05$. Correlations between variables were assessed using Spearman's rank correlation coefficient ρ (rho). Correlations between antibody concentration in umbilical cord blood samples and variables of interest, including *time of first* or *second vaccination, mean interval between first* or *second vaccination and delivery in weeks, maternal age* and *BMI* were examined. The correlation between antibody concentrations and gestational week at vaccination and time between vaccination and birth was additionally analysed by simple linear regression analysis. A graphical illustration of regression analyses was performed with GraphPad Prism Version 9.3.1 (350), December 7, 2021.

All data was entered by medical residents of the Obstetrics Department of the University of Münster after a personal medical interview, aside from follow-up data, which was collected by phone interview. Validation controls were regularly performed by the study organisation team of the CRONOS study [15].

Results

Study population

Of the 103 women participating in the CRONOS Satellite, 70 women and their 74 newborns (4 twin pregnancies) were included in the final evaluation (▶ **Fig. 1**). The demographic characteristics and full medical history of the study population are displayed in ▶ **Table 1**. The median age (interquartile range/IQR) of partici-

▶ **Table 1** Demographic and medical data of the study population.

Parameter	Value
Median maternal age (IQR*)	33.5 (32.0–37.0)
Ethnic	
▪ Northern European	92.9% (65/70)
▪ South European	2.9% (2/70)
▪ Eastern European	2.9% (2/70)
▪ South African	1.4% (1/70)
BMI (kg/m^2)	23.5 (22.0–28.0)
▪ Normal < 25	61.5% (43/70)
▪ Overweight 25–29.9	21.5% (15/70)
▪ Obese > 30	17.0% (12/70)
Smoking status	
▪ No	96.0% (67/70)
▪ Yes	4.0% (3/70)
Gravida (IQR*)	2.0 (1–3)
Parity (IQR*)	1.0 (0–1)
Pregnancy	
▪ Singleton	94.0% (66/70)
▪ Twin	6.0% (4/70)
Median pregnancy week at delivery (IQR*)	40.0 (39–41)
Concomitant disease	
▪ No	49.0% (34/70)
▪ Yes	51.0%** (36/70)
– Cardiovascular	8.6%** (6/70)
– GDM	15.7%** (11/70)
– Coagulation disorder/ state after thrombosis	11.4%** (8/70)
– Other	22.9%** (16/70)

* Abbreviation: IQR, interquartile range

** Percentages of different organ systems do not add up to the total percentage of concomitant disease as some women had more than one comorbidity. 'Other' includes neurological, gastrointestinal, endocrinological, pulmonary system or pre-existing diabetes mellitus.

▶ **Table 2** Vaccination history of the study population.

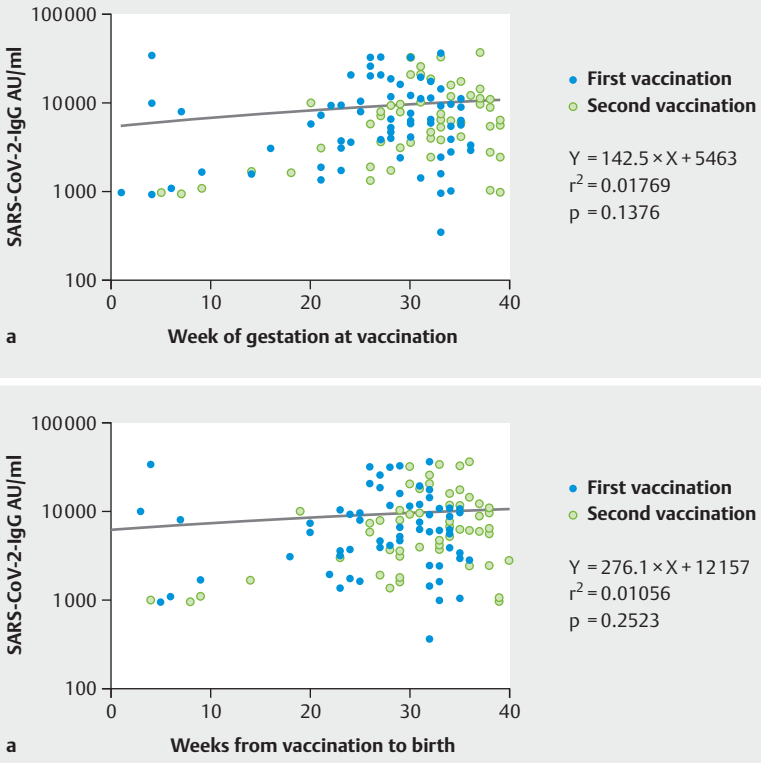
Parameter	Value
Vaccine type	
▪ BNT162b2 (Pfizer-BioNTech)	89.0% (62/70)
▪ mRNA-1273 (Moderna)	10.0% (7/70)
▪ Unknown	1.0% (1/70)
Vaccination in	
▪ 1st trimester	10.0% (7/70)
▪ 2nd trimester	30.0% (21/70)
▪ 3rd trimester	60.0% (42/70)
Median week of gestation at	
▪ 1st vaccination (IQR*)	28.5 (23.0–33.0)
▪ 2nd vaccination (IQR*)	32.0 (28.0–35.8)
Median time interval in weeks between	
▪ 1st vaccination and delivery (IQR*)	11.0 (7–16)
▪ 2nd vaccination and delivery (IQR*)	7.0 (4–11)
Reason for vaccination	
▪ Pregnancy only	74.3% (52/70)
▪ Other medical conditions	5.7% (4/70)
▪ Work in health care	17.1% (12/70)
▪ Work with children	2.9% (2/70)
Symptoms after vaccination/ vaccination reaction	
▪ No	21.0% (15/70)
▪ Light (e.g., local pain)	56.0% (39/70)
▪ Medium (e.g., fever, headache max. 48 h)	9.0% (6/70)
▪ Severe to critical symptoms	0.0% (0/70)
▪ Unknown	14.0% (10/70)

* Abbreviation: IQR, interquartile range

pants was 33.5 (32.0–37.0) years, and in 51% of the cases (n = 36/70) the mother had a pre-existing or concomitant medical condition (▶ **Table 1**). Pregnancy was the single most common reason why women decided to get vaccinated (74.3%, n = 52/70). The majority of women (89%, n = 62/70) were vaccinated with BNT162b2 and all but one (99%, n = 69/70) with an mRNA vaccine. All women were double-vaccinated at the time of birth, and the longest interval between last vaccination and delivery was 36 weeks. However, the exact week of gestation at second vaccination was documented in only 80% (n = 56/70) of the cases. No severe side effects were reported, and only 9% of women reported medium side effects (e.g., fever or headache lasting a maximum of 48 h). The vaccination history of the study population is displayed in ▶ **Table 2**.

Presence of IgG antibodies to the receptor-binding domain of the SARS-CoV-2 spike protein and exploratory data analysis

IgG antibodies to the receptor-binding domain of SARS-CoV-2 spike protein were detected in all specimens (n = 74/74, among them 2 pairs of twins). Twin pregnancies were represented as one newborn in exploratory data analysis to avoid bias (n = 70). The titre concentration between twins did not differ strongly (values from dichorionic diamniotic pregnancies: *11 197.9 AU/ml*/11 836.4 AU/ml, *21 211.5 AU/ml*/20 474 AU/ml, *6548.7 AU/ml*/no blood sample, values from monochorionic diamniotic pregnancy: *3151.6 AU/ml*/2984.6 AU/ml). The highest value *in italics* was considered in the statistical analysis. None of the parameters of interest (week of gestation at vaccination, time interval between vaccination and birth, maternal age and BMI) showed a meaningful correlation to cord blood antibody concentrations (▶ **Table 3**). Regression analysis demonstrates no meaningful correlation of antibody concentrations with time of vaccination during pregnancy or interval between vaccination and birth (▶ **Fig. 2a** and **b**).



▶ **Fig. 2** SARS-CoV-2 antibody concentration in cord blood at birth **a** as a function of week of gestation at vaccination and **b** as a function of time interval between vaccination and birth.

▶ **Table 3** Spearman correlation coefficient analysis of SARS-CoV-2 IgG antibodies to the receptor-binding domain of the SARS-CoV-2 spike protein after vaccination (n = 70).

Variable	Correlation coefficient (ρ)*	P-value**
Week of gestation at		
▪ 1st vaccination	0.060	0.620
▪ 2nd vaccination	0.247	0.066
Mean time interval in weeks between		
▪ 1st vaccination and delivery	− 0.026	0.832
▪ 2nd vaccination and delivery	− 0.202	0.136
Maternal age	− 0.118	0.331
BMI	0.118	0.332

* Positive or negative ρ values imply a positive or negative association, respectively. Value spectrum: ± 0.6–0.8 (strong association), ± 0.4–0.6 (moderate association), ± 0.2–0.4 (weak association), ± 0–0.2 (very weak association).

** $p \leq 0.05$ was considered significant.

Follow-up

More than three quarters of the women (81%, n = 57/70) participated in the follow-up 4–6 weeks after delivery. In 5% (n = 3/70) no valid phone number was documented, and 14% (n = 10) had not yet completed the follow-up at the time of data evaluation.

In follow-up surveys no adverse drug events were reported during the postpartum period of 46 weeks. No malformations in children have been reported in association with the vaccine.

Discussion

Transplacental transfer of maternal SARS-CoV-2-specific antibodies after infection in pregnancy has been proven [8 – 11]. Data on transplacental transfer after SARS-CoV-2 vaccination is insufficient and is limited to case series of women vaccinated with BNT162b2 in the third trimester of pregnancy [9, 13] and two case reports [10, 12 – 14]. Most importantly, in this study we were able to demonstrate transplacental passage of antibodies to the receptor-binding domain of the SARS-CoV-2 spike protein after vaccination in pregnancy in all cases. Moreover, antibody concentrations were not dependent on gestational week at vaccination. No adverse outcome, including foetal malformation, was reported, even after vaccination in the first trimester.

Antibodies in newborns after maternal SARS-CoV-2 infection during pregnancy have been detected in 63–87% of cases [8, 9, 11]. In our cohort the detection rate after vaccination was 100%.

This fact is relevant for patients who are hesitant regarding vaccination in pregnancy, as vaccination during pregnancy not only protects against a severe maternal course of COVID-19 but also provides the newborn with antibodies. These can potentially shield them from postnatal SARS-CoV-2 infection. As SARS-CoV-2 antibodies in adults after vaccination decrease over time [19, 20], one would expect fewer antibodies in umbilical cord blood after vaccination in early pregnancy and a longer interval between vaccination and delivery. In the present study, however, regression analysis showed no significant dependence of antibody titres on the above variables and Spearman's rank correlation coefficient showed only a weak or very weak correlation. A possible explanation is that decreasing antibody concentration in maternal plasma over the course of time is counteracted by a higher transplacental transfer rate in the later weeks of pregnancy, resulting in an increase in the fetomaternal antibody ratio [11]. Nevertheless, the uneven distribution of gestational age at vaccination with underrepresentation of vaccination in the first trimester of pregnancy does not allow a final conclusion.

It is furthermore remarkable that vertically transferred antibodies could be detected 36 weeks after the last vaccination, proving that maternal humoral immunity can last longer than 6 months. From this information, it can be inferred that a vaccination at any point in pregnancy will help confer passive immunisation on the newborn.

Recommendations on booster vaccination during pregnancy vary. The CDC and ACOG suggest that pregnant women may receive a COVID-19 vaccine booster shot in pregnancy [5, 21]. The Standing Committee on Vaccination at the Robert Koch Institute in Germany (STIKO) recommends a booster vaccination during pregnancy from the 2nd trimester onward and the German Society of Gynaecology and Obstetrics (DGGG) recommends a booster vaccination at least three months after the last dose [22]. Our data supports the general recommendation in regard to potential neonatal immunity through maternally derived, transplacentally acquired antibodies. A booster vaccination at any time during pregnancy could increase neonatal antibody titres.

Although SARS-CoV-2 infection is not known to be widespread in newborns and infants, this paediatric population is particularly vulnerable to severe disease following SARS-CoV-2 infection [23], highlighting the urgency of understanding the factors that contribute to neonatal SARS-CoV-2 immunity.

The main limitation of our work is the small sample size in which specific subgroups were not sufficiently represented, such as women vaccinated early in pregnancy or vaccinated with mRNA-1273. Although this is one of the largest cohorts on the topic, it is possibly too small to detect clinical variables that influence neonatal SARS-CoV-2 IgG antibody concentrations. A maternal SARS-CoV-2 infection before or during pregnancy, which could influence neonatal IgG levels, was excluded only by medical history. Moreover, the study is limited by an inability to assess persistent immunity and antibody transfer ratios, as well as the exclusive focus on antibody titres rather than neutralising antibodies.

The strengths of this work include high data security and quality, as our project was part of the centrally designed CRONOS study. Moreover, participants were recruited after personal medical interview, which ensures correct data collection. The unanimous detection of IgG antibodies to the receptor-binding domain of the SARS-CoV-2 spike protein in all umbilical cord blood samples, irrespective of maternal medical or vaccination history, allows the definitive statement that after vaccination in pregnancy maternal antibodies do vertically transfer to the newborn.

Future studies with larger patient cohorts and longer follow-up times for mother and child, including regular determination of antibody levels of both, could give an insight into placental transfer ratios after COVID-19 vaccination during pregnancy. Moreover, determination of neutralising antibodies may enhance our ability to understand whether and to what extent vertically transferred immunity after vaccination protects the newborn from SARS-CoV-2 virus. Future studies should also define the optimal window for primary immunisation or booster immunisation to ensure neonatal immunity. Moreover, data collection on vaccination in the first trimester is necessary, as postponement of vaccination or booster vaccination during the ongoing pandemic poses a health risk for vulnerable populations, e.g., women with relevant concomitant diseases.

In conclusion, our data provides evidence for the presence of antibodies against SARS-CoV-2 in all analysed umbilical cord blood samples after maternal vaccination at any time during pregnancy. This is an additional argument when counselling women to get vaccinated during pregnancy.

Clinical trial identification number: DRKS00021208
URL: https://www.drks.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00021208

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Conflict of Interest

The authors declare that they have no conflict of interest.

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