

## Study finds COVID vaccine for pregnant women safe for newborn infants

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Results of the largest study, to date, on the safety of newborn babies whose mothers were vaccinated against COVID-19 during pregnancy show no increased risks for babies, and for some serious neonatal



complications—lower risks. The study is a collaboration between Swedish and Norwegian researchers and is published in the journal *JAMA*.

COVID-19 vaccination in pregnancy was not associated with any increased risks in <u>newborn infants</u>. On the contrary, the study of nearly 200,000 newborns in Sweden and Norway showed that babies born by women who chose to be vaccinated were less likely to suffer serious complications, including death. The mortality rate was only half as high in babies whose mothers had been vaccinated.

"We made several attempts to explain this finding. A direct vaccine effect is unlikely. Previous studies have shown that the vaccine does not cross the placenta and that it cannot be found in <u>umbilical cord blood</u>," says Mikael Norman, professor of pediatrics and neonatology at the Department of Clinical Science, Intervention and Technology, Karolinska Institutet and first author of the study.

Instead, the researchers have adjusted for several background factors that were unevenly distributed in the two groups of women. They also conducted seven different subgroup analyses of women and newborns.

"No matter how we look at it, the finding remains and therefore, we cannot say what the lower risk of death among infants of vaccinated women relates to," says Mikael Norman.

The researchers used national registers in both countries and included 98% of all newborn babies of women who became pregnant after the vaccines became available. All births from gestational week 22 and onward were included in the study. The first baby was born in June 2021 and the last one in January 2023. All babies were followed up for at least one month or as long as they were admitted to a neonatal unit.



In total, the study included 196,470 newborns where 48% of the mothers had been vaccinated with one or more doses of an mRNA vaccine against COVID-19. Almost 80% had received the Pfizer/BioNTech vaccine and just over 20% the <u>vaccine</u> from Moderna.

In addition to lower <u>infant mortality</u>, the researchers also found a significantly lower risk of two other serious complications in infants born to mothers who had been vaccinated. In total, fifteen neonatal complications and conditions were studied.

"We saw lower rates of cerebral hemorrhages and hypoxia-ischemic conditions of the brain in the newborns of vaccinated than in babies of unvaccinated in pregnancy, while the incidence of other bleedings, blood clots or inflammation in various organ systems did not differ between the groups," says Mikael Norman.

Despite the fact that the pandemic is over, the study and the results are of great importance for <u>health care professionals</u> offering counseling, authorities issuing recommendations, and above all, for anyone who will become pregnant in the future, says Mikael Norman.

"COVID-19 is still present in society and is probably something we will have to deal with for a long time. It is therefore very important for the one hundred thousand women who become pregnant every year in Sweden, and the 130 million in the world, to know that vaccination with mRNA-vaccines against COVID-19 is safe for their babies. We found no increased risks, if anything, infants to vaccinated women had lower risks for some severe outcomes."

**More information:** Mikael Norman, Neonatal Outcomes After COVID-19 Vaccination in Pregnancy, *JAMA* (2024). DOI: 10.1001/jama.2023.26945



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