

Experts Warn of ‘Huge Risk’ as Moderna Launches COVID Vaccine Trials for Pregnant Women

The vaccine maker is launching a clinical trial to assess safety of its vaccine in pregnant women, despite 133,000 pregnant women having already received a COVID vaccine prior to trials.

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Moderna will begin studying its COVID vaccine in pregnant women, according to a posting on [ClinicalTrials.gov](#). The observational study, expected to begin July 22, will enroll about 1,000 females over age 18 who will be studied over a 21-month period.

Women who [received a Moderna vaccine](#) during the 28 days prior to their last menstrual period, or at any time during pregnancy, are eligible.

The [brief summary](#) of the trial states the main goal is “to evaluate the outcomes of pregnancy in females exposed to the [Moderna](#) COVID-19 vaccine (mRNA-1273) during pregnancy.”

The study will measure the number of participants who have infants with suspected major and minor congenital malformations, the number of participants with any pregnancy complications, the number of participants with any pregnancy outcomes and the number of participants with infant outcomes, [Fox Business reported](#).

Currently, the Centers for Disease Control and Prevention (CDC) [says](#) pregnant women can get a [COVID](#) vaccine. But the CDC also acknowledges there is limited data available about the safety of COVID vaccines for people who are pregnant.

The CDC [website states](#):

“No evidence exists of risk to the fetus from vaccinating pregnant people with non-replicating vaccines in general. However, the potential risks of COVID-19 vaccines to the pregnant person and the fetus are unknown, because these vaccines have not been extensively studied in pregnant people.”

According to the [CDC’s website](#), as of June 29, data collected from the CDC and U.S. Food and Drug Administration’s (FDA) [safety monitoring systems](#) had not identified “any safety

concerns for pregnant people who were vaccinated or their babies,” but the agencies stressed findings are preliminary.

Experts urge caution

“Pregnant women are taking what may be a huge risk with the COVID vaccine,” said [Jennifer Margulis](#), Ph.D., author of “[Your Baby, Your Way](#).”

Margulis told [The Defender](#) in an email:

“We have no long-term studies showing it’s safe. We made this mistake with [diethylstilbestrol](#)— a synthetic estrogen thought to be safe during pregnancy that was later found to cause aggressive (and sometimes lethal) cancer in the genitals of young teenagers whose moms had been prescribed it.”

Margulis believes it is irresponsible, and even unethical, to assert that we know the Moderna vaccine is safe for pregnancy.

She said:

“It’s imperative to use the [precautionary principle](#) when it comes to this highly experimental technology. The burden of proof must be on the intervention. We have no evidence that this is safe. But [ample evidence](#) shows that it is dangerous to expose pregnant women and unborn babies to drugs and interventions that can disrupt immunity.”

The [most recent data](#) from the Vaccine Adverse Events Reporting System ([VAERS](#)) — one of the safety monitoring systems co-managed by the FDA and CDC — has received [2,678 reports](#) of adverse events related to COVID vaccines in pregnant women, including 994 reports of [miscarriage or premature birth](#) between Dec. 14, 2020 and July 2, 2021.

Data assessing safety of COVID vaccines in pregnant women is lacking

Since the FDA in December 2020 granted [Emergency Use Authorization](#) (EUA) for COVID vaccines, the CDC has [recommended](#) pregnant women be [offered the vaccine](#) — despite the fact that pregnant women were [excluded from preauthorization clinical trials](#), and despite the limited data on safety and efficacy of COVID vaccines during pregnancy.

In January, the World Health Organization said pregnant women [should not receive a COVID vaccine](#). A week later, the agency [changed its guidance](#) and advised everyone to take the shot, including pregnant women.

According to a March 1 [safety update](#) by the CDC’s vaccine safety panel on the COVID vaccine and pregnancy, post-authorization safety monitoring and research are the primary ways the CDC obtains safety data on COVID vaccination during pregnancy.

In other words, the vaccine is given to pregnant women before studies determine whether the vaccine is safe for that population. The [CDC’s website](#) states that 133,466 pregnant women have already received a COVID vaccine as of July 12.

“It seems bass-ackwards to release the vaccine to pregnant women before doing a

clinical trial or proper animal studies,” said **Lyn Redwood**, RN, MSN and president emerita of [Children’s Health Defense](#).

Redwood said:

“Does the vaccine lipid nanoparticle cross through the placenta? If so, what is the effect on the offspring with regard to morbidity or mortality? These are questions we need to be asking. Pregnancy used to be a time where we were to protect the mother and baby from any potential harms, especially during the first trimester.”

In April, the CDC started actively recommending all pregnant women get vaccinated for [COVID](#) based off of one retrospective study published in the [New England Journal of Medicine](#).

The retrospective study, “[Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons](#),” relied on multiple vaccine surveillance systems from December 2020 to February to assess the safety of the [Pfizer-BioNTech](#) and Moderna vaccines in more than 35,000 pregnant women who had chosen to get vaccinated after the vaccines were approved for emergency use.

A Utah teen remains hospitalized with three blood clots in and near his brain that developed after he received the first dose of Pfizer’s COVID vaccine.
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— Robert F. Kennedy Jr (@RobertKennedyJr) [May 11, 2021](#)

The authors of the study stated they found no increased risks during pregnancy, or birth complications or identifiable risks to the fetus among those who received the vaccine.

Shortly after, the [CDC updated](#) its official recommendations that pregnant women receive a COVID vaccine based on the study’s data compiled over the course of two months.

CDC Director **Rochelle Walensky** highlighted the findings at an [April 23 briefing](#) where she stated the “CDC [recommends](#) that pregnant people receive the COVID-19 vaccine.”

According to **Dr. Brian Hooker**, Ph.D., P.E., Children’s Health Defense chief scientific officer and professor of biology at Simpson University, the results regarding pregnancy loss were highly skewed.

Hooker told The Defender:

“The majority of the denominator received their vaccine in the third trimester where pregnancy loss would be much less. Most of the pregnancy losses were in the first trimester and there are no data on the outcomes of the other women who received their vaccine in the first trimester (i.e., whether they carried to term), or data on the temporal relationship between receipt of the vaccine and miscarriage which is suspect.

“There is also no data regarding any incidence of clotting disorders reported or any type of blood malady that may occur (e.g., spotting or bleeding during pregnancy), and very

limited treatment of neonatal outcomes (no APGAR score, etc.) due to the very limited duration of the study.

“This is typical ‘nothing to see here’ CDC propaganda and the paper is essentially meaningless regarding pregnancy outcomes. In order to adequately assess these outcomes, pregnancies need to be followed to term.”

Although Moderna’s clinical trial is expected to begin July 22, [Pfizer](#) and [J&J](#) already are conducting clinical trials testing the safety and efficacy of their vaccine in pregnant women.

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