

About the BabyCOVE Study

- The purpose of the BabyCOVE Study is to evaluate an investigational vaccine that may protect infants from getting sick if they come into contact with SARS-CoV-2 (also called coronavirus), which causes COVID-19.
- To join this research study, your baby must be between 12 weeks and less than 6 months of age and in good health. All study participants will receive study-related medical care from the study doctor while in the BabyCOVE Study.
- The study doctor and study team will talk to you about additional medical support that your baby will receive if they experience any COVID-19 symptoms at any time while in the study.
- Insurance is not needed to join this clinical research study. Compensation may be provided for your family's study-related time.

Diseases do not discriminate — and neither should clinical trials. Moderna is committed to researching safe and effective mRNA-based vaccines and therapies to bring better health and living to people of all ages, sexes, and backgrounds.

About the Investigational Pediatric Vaccine

The vaccine being evaluated in the BabyCOVE Study is Moderna's "bivalent" (addressing 2 viral strains at the same time) investigational COVID-19 vaccine. It is being evaluated at 2 dosing levels to find out which is the safest and most effective dose for infants. Moderna is studying this investigational vaccine to understand if it can help a body's immune system protect against COVID-19.

Normally, vaccines for viruses are made from a weakened or inactive (not live) virus, but this investigational pediatric vaccine is different. It is made from an instructional molecule called mRNA, which tells cells how to make protein. The hope is that these proteins will know how to fight the virus, should it enter the body. Your baby cannot get infected with SARS-CoV-2 or get COVID-19 illness from the investigational pediatric vaccine.

If your baby is eligible and you decide to participate, your family, along with more than 700 other families, would be helping researchers learn more about Moderna's investigational pediatric vaccine, which may help protect infants from getting sick if they come into contact with the virus that causes COVID-19, including its Omicron variant. Your baby's participation may contribute to a potential solution that helps solve the evolving COVID-19 pandemic, which has affected the entire world. The study team will talk about signs and symptoms, including those of possible COVID-19, that you need to watch for. If your baby has any of these signs or symptoms, you should call the study team right away, even if you don't think the signs or symptoms are serious.


About the Placebo

In order to understand if the investigational vaccine works, it is being compared to a saltwater placebo (a solution that looks just like the vaccine but contains no active vaccine). Every study participant will receive the same level of quality care regardless of whether they receive the investigational pediatric vaccine or the placebo.

Thank you for your interest in the BabyCOVE Study.

We understand that any decision regarding your baby's health is a big one. By taking part in this study, your baby could make a difference for your family, your community, and people everywhere.

To learn more, visit BabyCOVEStudy.com or contact the participating site listed here:

 **TANNER CLINIC** Eva Pitchford
Clinical Research Coordinator
801-773-4840 ext. 3642
Doctors: Forbush, Eberhard, Hutchinson



You'll always remember the time your baby made a mark on the world.

While COVID-19 is relatively new to us, the disease has been in your baby's world since the day they were born. And although we've made great strides in research and vaccine development for COVID-19, there is still no approved or authorized protection for babies under 6 months old, leaving them vulnerable at daycare, at family functions, and even at home as older siblings head back to school.

Through the BabyCOVE Study, you can advance research that may be able to provide your little one some protection. And you both could potentially make a big difference toward protecting babies around the world and possibly even future generations of your family.

About Vaccine Studies

It is very important to remember these things if you are thinking about having your baby join a vaccine study:

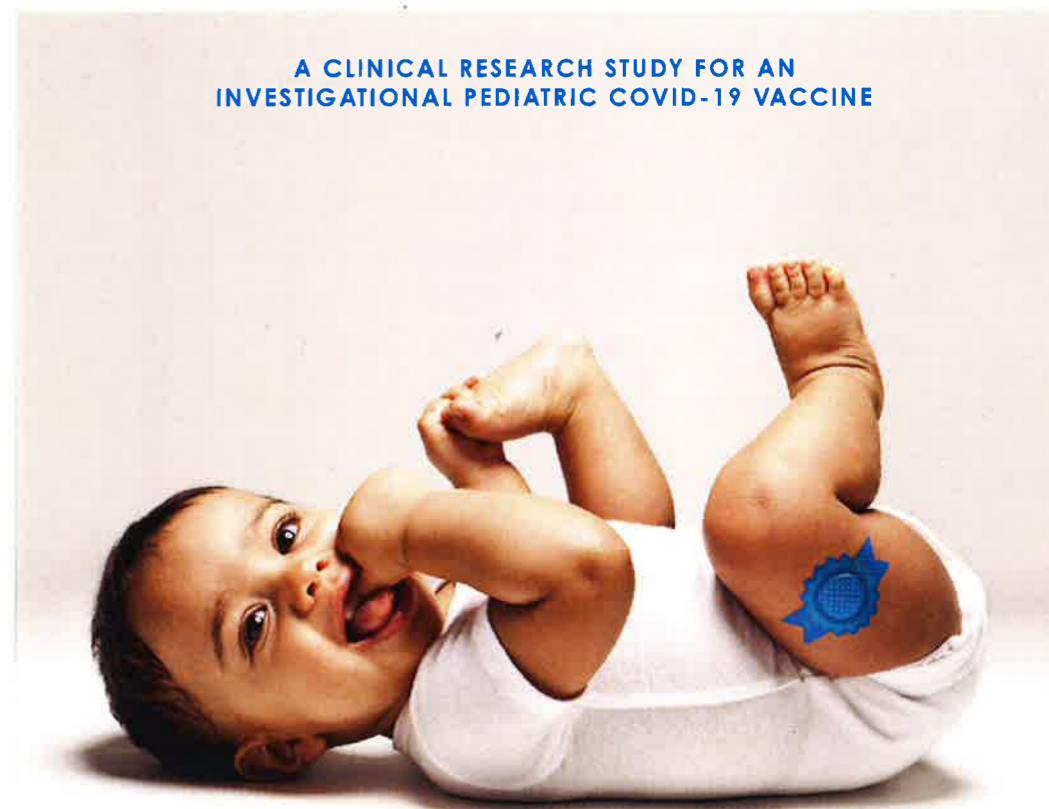
- The investigational pediatric vaccine has not yet been approved for use in infants. This means we are still researching the product and we do not know if it is effective and safe to use. We do not know if it will prevent SARS-CoV-2 infection or reduce the severity of COVID-19 illness.
- All vaccines may have some side effects, and this is true for this investigational vaccine too.
 - Based on experience in older children and adults, common risks include fever, chills, rash, aches and pains, nausea, headache, and dizziness. These issues usually go away within a few days, and your baby can still go about their daily activities
- Throughout the study, we will be monitoring participants closely for any side effects.

Withdrawing from the BabyCOVE Study

You have the right to withdraw your baby from the study at any time, for any reason. The study doctor or sponsor also has the right to discontinue your baby's participation at any time in the interest of their safety or if they do not continue to meet requirements for participation.

We understand that, as a parent or guardian, enrolling your baby in a clinical research study is a big decision. Thank you for considering the BabyCOVE Study.

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A CLINICAL RESEARCH STUDY FOR AN INVESTIGATIONAL PEDIATRIC COVID-19 VACCINE

Someone little can make a big difference.

Your baby could be part of important research for an investigational coronavirus (COVID-19) vaccine.

TANNER CLINIC



moderna

BabyCove STUDY