

KidCOVE Study Talking Points



What Is the Purpose of the KidCOVE Study?

The purpose of the KidCOVE Study is to test a vaccine that may protect children from getting sick if they come into contact with SARS-CoV-2 (also called coronavirus), which causes COVID-19.



What Is the KidCOVE Study?

The KidCOVE Study is a clinical trial that is testing a study vaccine for the prevention of COVID-19. Researchers will measure your child's immune response to the vaccine by collecting blood samples. These samples will be tested for natural proteins that are called antibodies. Checking your child's antibody level helps researchers know how well the study vaccine is working.

The study doctor and study team will monitor your child's health throughout the study.



Who Can Participate?

Children six months to under 12 years of age may be eligible for the KidCOVE Study.



How Many Participants Will Be in the Study?

Approximately 13,275 children will enroll in this clinical research study.



How Long Will My Child Be in the Study?

Participation in this study will last around 14 months and includes phone calls with the study team and up to seven visits to the study site.



What Happens during the Study?

Your child will have two injection visits, which will be 28 days apart. If your child is enrolled in the first part of the study, you will know that they are receiving the study vaccine. If your child is enrolled in the second part of the study, they will be chosen at random to receive either the study vaccine or the placebo. There is a 75% chance your child will receive the study vaccine and a 25% chance they will receive the placebo. Your family will not know which option your child has been assigned if enrolled in the second part of the study.

You and your child will be asked to return to the study site three to four more times, depending on their enrollment assignment. These visits will occur 15 days, one month, six months, and 12 months after the second injection.

Your child will have two telemedicine visits – about one week after each injection. During these calls, the study team will check how your child is feeling. After that, the study team will call you once a month during the months your child does not have a study site visit.

You will be asked to complete electronic diary (eDiary) entries for the duration of the study to report any COVID-19 symptoms your child experiences.

Your child will be closely monitored by the study team if any symptoms of COVID-19 are reported at any time throughout their participation.

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.



What Is the Study Vaccine?

The vaccine being tested in the KidCOVE Study is called mRNA-1273, and it is being tested at three dosing levels to find out which is the safest and most effective dose for children. Moderna is studying this vaccine to understand if it can help a body's immune system protect against COVID-19.

Often, vaccines for viruses are made from a weakened or inactive (not live) virus, but the mRNA-1273 study vaccine is different. It is made from messenger ribonucleic acid (mRNA), which is an instructional molecule that naturally occurs in the body and tells cells how to make protein. In this case, the protein is a small part of the virus that is thought to help the body's immune system protect itself if it ever comes across SARS-CoV-2.

In the second part of the study, the study vaccine is being compared to a placebo. The placebo in this study is a saltwater solution that looks just like the study vaccine being tested but does not contain any active ingredients.

Each participant will receive a shot (either the study vaccine or the placebo) at Visit 1 (Day 1) and then again at Visit 3 (Day 29).



How Will My Child Feel after the Vaccinations?

All vaccines have some side effects, and your child may experience side effects in this study. This is the first time that the study vaccine will be tested in children under 12 years old. In other studies of adults receiving vaccines similar to mRNA-1273, the most common side effects were fever, headache, muscle aches or pain, joint aches or pain, tiredness, nausea/vomiting, and chills.

After each injection, your child may have pain or redness and hardness of the skin at the injection site. If the injection was given in the arm, underarm gland swelling may also occur on the arm where the study vaccination was given. If the injection was given in the leg, as is commonly done for babies, there may be swelling in the groin.

Most side effects go away within a few days after the injection, and your child should still be able to go about their daily activities. Not everyone has side effects, and these side effects may not be experienced after every dose.



What Are the Risks and Benefits?

There may be no direct benefit to your child from participating in this study. However, information learned from the study may help researchers learn more about vaccines to prevent COVID-19 and may help bring an end to the COVID-19 crisis.

Please ask the study team any questions you have about study participation.



Is There a Cost to Participate?

The study vaccine and study-related tests and procedures will be provided at no cost to your family.



Can I Withdraw My Child from the Study?

You can withdraw your child from the study at any time. Participation is completely voluntary, and you can change your mind about your child's participation. Withdrawing from the study will not affect your child's future medical care.

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