

# Study Participation Overview

## The Importance of Participation

The coronavirus (COVID-19) pandemic is like nothing we've seen in more than a century, and it has altered each and every one of our lives. Parents and caregivers just like you are waiting on a vaccine so children can return to school, the playground, and afterschool activities. And now, your child could be a part of important research on a COVID-19 vaccine.

By enrolling your child in the KidCOVE Study, your family is contributing to a potential solution that could solve this global health crisis.

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, which causes COVID-19. The KidCOVE Study is evaluating:

- The safety of the study vaccine (called mRNA-1273), which is given to your child in two doses 28 days apart
- The effectiveness of the study vaccine at preventing illness after exposure to SARS-CoV-2
- The occurrence of COVID-19 infection after vaccination with the study vaccine or the placebo

## In order to participate, your child must:

- **Be between six months old and less than 12 years old and in good health**
- **Not have a positive COVID-19 test within two weeks prior to receiving the first vaccination**
- **Be free from exposure to someone with SARS-CoV-2 infection or COVID-19 within two weeks prior to receiving the first vaccination**
- **Not have received an investigational vaccine or treatment for COVID-19**
- **Be willing and able to comply with all study requirements**

**There are additional eligibility requirements, which the study doctor can explain to you.**



## About the KidCOVE Study

This study lasts approximately 14 months and includes phone calls, telemedicine visits, and up to seven visits to the study site.



Your child will have two injection visits, which will be about 28 days apart.



You and your child will be asked to return to the study site three to four 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 – where the study team will call to check how your child is feeling. The study team will also call you once a month after that, during the months your child does not have a study site visit, to discuss safety-related information.



You will also 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.

Participation in the KidCOVE Study is completely voluntary. You may withdraw your child from the study at any time, for any reason.

### About 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.

Normally 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.

To date, more than 30,000 adults and children over the age of 12 have taken part in the research for mRNA-1273. There have been no serious side effects observed or reported by adult participants in previous phases of the study.

### About the Placebo

In order to understand if the study vaccine works, the mRNA-1273 study vaccine is being compared to a saltwater placebo (a solution that looks just like the study vaccine but contains no active vaccine). Your child will receive the same level of quality care regardless of if they receive the study vaccine or the placebo.

### How Your Child Will 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 investigational vaccine will be tested in children less than 12 years of age. In other studies of people 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.

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.

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We know that decisions regarding your child are never taken lightly, and we appreciate your consideration of the KidCOVE Study. Your child's participation could make a difference that changes the world.

To learn more, visit [KidCOVEStudy.com](https://KidCOVEStudy.com) or contact the participating site listed here.