

Home / Participate in a Study / Current Studies / KidCOVE COVID-19 Study

Current Studies

KidCOVE COVID-19 Study

Participants needed: 6 months - less than 6 years old

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.

To be eligible, your child must:

- Be between six months old and less than six 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

What will my child have to do?

- 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.

For more information:

KidCOVE Brochure (https://centerforvaccinology.ca/wp-content/uploads/2021/11/mRNA-1273-P204_Rec-

Brochure V1 08February2021 ENG.pdf)

KidCOVE Study Talking Points (https://centerforvaccinology.ca/wp-

content/uploads/2021/11/20ck Moderna KidCOVE Study-Talking-Points v3 080421.pdf)

<u>KidCOVE Study Fact Sheet (https://centerforvaccinology.ca/wp-content/uploads/2021/11/mRNA-1273-P204_Study-Fact-Sheet_V1_08February2021_ENG.pdf)</u>

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