

THE COVID-19 VACCINE PEDIATRIC STUDY

Parents: Your Child Can Help Make a Difference



Learn more about
this vaccine research
study to see if it is
right for your child.

About This Study

This study compares an investigational (study) COVID-19 vaccine against a placebo (injection with no active ingredient) to learn if the vaccine can produce an immune response against COVID-19, and if it is safe, in children 6 months to 4 years old.

Healthy children who are 6 months to 4 years old can participate. The study will enroll over 4,600 participants. All participants will have the opportunity to receive the COVID-19 study vaccine during their time in the trial.

An Important Contribution

Every modern vaccine and medicine we have today was first tested in clinical trials involving hundreds to thousands of people before becoming available to the public.

Currently there are no approved COVID-19 vaccines available for children. Before one can be approved, COVID-19 vaccines need to be studied in a clinical trial that involves children. While fewer children have been sick with COVID-19 compared to adults, children can get sick from COVID-19 and can spread the virus to others, even if they have no symptoms. Although most children with COVID-19 have mild symptoms or have no symptoms at all, some children can get severely ill.

Joining a clinical trial is an important and personal decision for you and your family. We hope it is one you and your child will consider.

What Can My Child And I Expect?

- Your child will be randomly assigned (by chance) to receive either the COVID-19 study vaccine or placebo (injection with no active ingredient). This assignment will be made by a computer and not by the study team. Neither you nor the study doctor will know if your child is receiving the study vaccine or a placebo.
- Two thirds of the participants will receive the COVID-19 study vaccine, and one third will receive the placebo.
- Your child's time in the study will last for about two years.
- The first 2 visits are when your child will receive the COVID-19 study vaccine or placebo through an injection in their arm.
- At the follow up visit 6 months after the second injection, you will learn if your child received the COVID-19 study vaccine or the placebo. If they received the placebo, they will be offered the COVID-19 study vaccine.
- Over the course of the 2 years, your child will have between 6 and 11 planned visits.
- You will be asked to track any changes in your child's health in an electronic diary (e-diary).
- You will be reimbursed for expenses (such as parking, meals, travel) and time related to completing the e-diary.



We Are Here To Help

We encourage you to talk to your child's doctor or the study team if you have questions about participating. Either of you can always change your mind and leave the study at any time.



Potential COVID-19 Symptoms

- Fever
- New Loss of Taste/Smell
- Difficulty Eating/Feeding (less than 4 years)
- New or Increased Cough
- Sore throat
- New or Increased Shortness of Breath
- Chills
- New or Increased Muscle Pain
- Abdominal Pain
- Vomiting
- Diarrhea



Contact Us

If you have questions or concerns about anything related to this study, please let the study team know. If you do not have questions now, you can always call or email the study team.



BAY COLONY
PEDIATRICS

Call: 281-614-2445 or 346-955-3561
Text: 844-398-2094 or 346-955-3561

www.baycolonypediatrics.com

COVIDVACCINESTUDY.COM



PARENTS: YOUR CHILD CAN HELP MAKE A DIFFERENCE IN THE FIGHT AGAINST COVID-19

Every modern vaccine was first tested in clinical trials involving hundreds to thousands of people before becoming available to the public. While progress has been made to develop COVID-19 vaccines for adults, currently there are no approved COVID-19 vaccines available for children. Before they can be approved, COVID-19 vaccines need to be studied in a clinical trial that involves children.

In this pediatric COVID study, we will learn if the COVID-19 study vaccine can produce an immune response against COVID-19, and if it is safe, in children 6 months to 11 years old. All participants will have the opportunity to receive the COVID-19 study vaccine during their time in the trial.

Participation in clinical trials by children of all backgrounds will make a difference by contributing to the development of vaccines for everyone. Joining a clinical trial is an important and personal decision for you and your family. We hope it is one you and your child will consider.

WHAT TO EXPECT



PARTICIPANTS WILL BE
**RANDOMLY
ASSIGNED**
(BY CHANCE) TO RECEIVE
THE COVID-19 STUDY
VACCINE OR PLACEBO*



PARTICIPANTS WILL
RECEIVE THEIR
2
INJECTIONS
3 WEEKS APART



PARTICIPANTS
WILL HAVE AT LEAST
4
**SCHEDULED
FOLLOW-UP VISITS**



PARTICIPANTS WILL TRACK
THEIR HEALTH AND
REPORT
ANY POTENTIAL COVID-19
SYMPTOMS

TWO THIRDS OF THE PARTICIPANTS WILL RECEIVE THE COVID-19 STUDY VACCINE AND ONE THIRD WILL RECEIVE THE PLACEBO. 6 MONTHS AFTER INJECTION 2, ALL PARTICIPANTS WILL LEARN IF THEY RECEIVED THE COVID-19 STUDY VACCINE OR PLACEBO. PARTICIPANTS WHO RECEIVED THE PLACEBO WILL HAVE THE OPTION TO RECEIVE THE COVID-19 STUDY VACCINE.

**[CONTACT A STUDY
TEAM MEMBER
TO LEARN MORE]**

[STUDY CLINIC]

[CONTACT PERSON]

[PHONE NUMBER]

[EMAIL ADDRESS]

[COVIDVACCINESTUDY1.COM]



INFORMATION FOR PARENTS

What is a clinical trial?

A clinical trial is a type of research study that collects new information and answers important questions about health and disease. All new medicines, including vaccines, need to be tested in clinical trials before they can be available to the public.

How do vaccines work?

Unlike most medicines, which treat or cure diseases, vaccines prevent them. A vaccine stimulates your immune system to produce antibodies, exactly like it would if you were exposed to the disease. After getting vaccinated, you develop immunity to that disease, without having to get the disease first. This is what makes vaccines such powerful medicine.

Is this a live vaccine being studied?

The study vaccine does not contain any live virus. The placebo is also an injection but it contains saline instead of active ingredients.

Has the COVID-19 study vaccine been studied in older children and adults?

The first trial for the COVID-19 study vaccine enrolled over 46,000 people 12 years and older and included 2,260 children aged 12-15 and 754 children aged 16-17.*

How can I learn more?

If you're interested in learning more about this clinical trial for your child, please visit **COVIDVaccineStudy1.com**.

*The study vaccine has received authorization for emergency use (EUA) by the U.S. FDA and other countries for individuals 16 and older. An EUA allows the investigational vaccine to be used during the current COVID-19 public health emergency. The vaccine has not been approved or licensed by the FDA but has been authorized for emergency use under an EUA to prevent COVID-19 in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the product's emergency use, unless the declaration is terminated, or authorization revoked sooner. Please see EUA Fact Sheet at <http://www.cvdvaccine.com>.