



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


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 they 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.

In this clinical trial, we will learn if the 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.

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**

<https://redcap.link/NJPedsCOVIDvaccine>



*injection with no active ingredient



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. Unlike most medicines, which treat or cure diseases, vaccines prevent them.

How do vaccines work?

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 children who are 12 years and older. The study vaccine has received authorization for emergency use (EUA) by the U.S. FDA and other countries. 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>.

How can I learn more?

If you're interested in learning more about this clinical trial for your child, please reach out to your local study site using the contact information on the other side of this handout. The study team will answer your questions and will ask questions to see if your child qualifies.

Deciding to join a clinical trial is a personal and important decision for you and your family. If you'd like to learn more, call the study site using the information on the other side of this handout.