

Participant Information Sheet (6-11 years): COV006

Investigating a Vaccine Against COVID-19 in children and teenagers

“A phase 2 study to assess the safety and immunogenicity of a recombinant adenovirus-based vaccine against Coronavirus Disease (COVID-19) in children aged 6-17 years of age”

We would like to invite you to take part in a study to help us see whether a vaccine works against a new disease. Taking part is your decision and we would like you to read this leaflet with a parent or guardian and ask them any questions you want.

Who are the Oxford Vaccine Group?

We are a team of doctors, nurses, scientists and assistants who work to stop children getting sick from germs using a medicine called a vaccine. Germs are tiny organisms (living things) which cause disease. They are so small you can't see them, but we can tell if we are affected by germs because we become unwell. Thank you for thinking about helping us.

What are vaccines?

Vaccines stop you getting poorly, and also help stop you spreading germs to your friends and family. So, they protect you and those around you.

What is this study?

In this study we want to give you two doses of vaccine and take some blood tests from you.

The purpose of this study is to test how well a new vaccine works against coronavirus, which represents a new disease. To test how well it works, we are going to give you either the new vaccine or one to prevent a different disease for Meningitis B, so that we can compare them. We will give you the vaccine with two small injections, into your arm. The vaccines will be given 1 or 4 months apart depending which group you are in. We won't be able to tell you which vaccine you have received until the end of the study, unless you are offered a coronavirus vaccine on a national immunisation programme before then.

We will also take blood before the injections and take some more blood tests in the next year to see how long the vaccine lasts for. This means we will know how often children need to get the vaccine to stay protected from coronavirus. We will take 5 or 6 blood tests in total.

We know some children don't like blood tests, so we will use a special cream or spray to make the test feel OK. We are asking at least 300 children to take part in this study from around the country.

We actively encourage children from Black, Asian and Minority Ethnic (BAME) groups to take part in this study.

What happens in the study

We would like to ask you and your parents some questions about yourself including:

1. How old are you?
2. Who is your family doctor?

The first time you come to visit us, we will then take some blood from your arm and give you a vaccine in your arm.

Taking blood can make people nervous, sometimes it can help if you have something fun to distract you, such as listening to music or reading. The whole appointment should take around 45 minutes.

On the second visit, we will also take some blood. You will get the second vaccination on your second visit.

We will take blood on three or four further visits during the year, to see how long the vaccine lasts for. One of these blood tests may take place between your vaccinations.

Do I have to take part in the study?

No, taking part in research is entirely **your** choice. You are free to change your mind at any time. You can stop taking part even if your Mum or Dad want you to continue.

What are the bad things about taking part?

After the blood test it may be sore and leave a bruise. The vaccine may also be sore.

Sometimes you may get a temperature after a vaccine. This is normal. If you develop a temperature within the first 48 hours of vaccination, with no other primary symptom of COVID-19, you will not need to miss school unless you have other symptoms of COVID-19.

What are the good things about taking part?

You are helping us to do research about a new germ, coronavirus, and how we can protect you and other people around you from it. Your results will help us to see whether we can protect children with this vaccine. We know that the vaccine works in adults but we don't know about children yet.

We are testing two vaccines, one for coronavirus and one for another disease. If you received the vaccine for the other disease during the study, we will try to give you the coronavirus vaccine if it is approved for use in children. We cannot guarantee this.

What will happen to the blood we take?

The blood is taken to a special laboratory which gives us results about whether or not the vaccine has worked, if you have had the new vaccine.

What will happen at the end of the research study?

When we know how well the vaccine has worked, we will have a better idea of whether we can protect coronavirus disease in children. This information may help the vaccine to be available to more children in the future. The results will be in a scientific magazine and we will send a letter to you and your parents so you know what we found out.

Thank you for thinking about helping us.