

Participant Information Sheet (12-15 years): COV006

Investigating a Vaccine Against COVID-19

“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, COVID-19, in children and young adults. 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 diseases which can be prevented by vaccines.

What are vaccines?

Vaccines are either proteins or molecules which are injected, and prevent you from becoming unwell from specific diseases. They help stop you spreading disease to your friends and family. So, they protect you, and those around you.

What is this study?

The purpose of this study is to test how well a new vaccine works against COVID-19, a new disease. The same vaccine has been tested in adults over 18 and is safe and effective. In this study we want to give you two doses of the COVID-19 vaccine and take some blood from you to see how many antibodies you make in response to the vaccine. Antibodies are small proteins in your blood which your body makes, to protect you from infection. You can either make antibodies in response to getting an infection or in response to getting a vaccine.

To test how well it works, we are going to give you either the new vaccine or an existing one for a different disease (Meningitis B), so that we can compare them. We will give you the vaccine with two injections (1 or 4 months apart) into your arm. This means that if you have the Meningitis B vaccine instead, you will be protected against Meningitis B. These vaccines will be given 1 month or 4 months apart depending which study group you are in. We will not be able to tell you which vaccine you are getting until the end of the study, as we are interested in comparing the side effect profiles of the two vaccines, and if we told you which vaccine you had received it might affect our results.

Before we give you the vaccine, we will also take blood to see whether you have had the new virus called ‘coronavirus’ before. However, we won’t be able to give you the results. Just because you have had the disease before does not mean you are automatically protected, but the information we get from you will provide important information into our understanding of the disease. **The data from this study may potentially only benefit a small group of children at high-risk of COVID-19 disease in the UK or children in other countries.**

We know some children don’t like blood tests, so we will use an anaesthetic cream or spray to make the test feel less painful. We are asking 261 children to take part in this study from around the country.

We actively encourage children from Black, Asian and Minority Ethnic communities to take part in this study.

Why have I been asked to take part?

We are asking you to take part because you are the right age and live in the <insert relevant region>, where we are doing the 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 GP?
3. Do you take any medications?

Your parents/guardian will fill in a questionnaire online to see if you are suitable to take part. Then we will ask you to visit us at the hospital.

We will ask you to make 5/6 visits to the <insert site name> . All visits (including those for vaccinations) will take place out of school time (and may fall during school holidays).

The first time you come to visit us, you and your parents or guardian will have the opportunity to ask as many questions as you want. We will then take some blood from your arm. We will give you numbing cream or spray to make the blood test more comfortable. Taking blood can make people nervous, it can help if you have something fun to distract you, such as listening to music or reading.

If you are a girl we will ask you to give you a urine sample to check you are not pregnant before we give you a vaccine in your arm. Because the vaccine hasn't been tested on pregnant women yet, anyone who could possibly be pregnant (regarded as aged 11 and above) must provide a urine sample to check before they receive a vaccination. This is a precaution only. We ask that all female participants who are sexually active use effective contraception for the duration of the study.

The whole appointment should take around 2 hours minutes. **All appointments will be at the weekend to make sure that no school is missed.**

On the second visit, we will repeat the blood test. Depending on which group you have been allocated to, you will receive a vaccination on your second or third visit. We will ask females aged 11 and over to repeat a pregnancy test before your booster.

The remaining visits will be spread out over the next year, which will only involve a blood test. They are to check how long the effects of the vaccine last for.

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 parents want you to continue.

What are the bad things about taking part?

After the blood test your arm may be sore and leave a bruise. The area where you received the vaccine may also be sore. Some side effects have been described but they are very rare.

Side effects that occurred during clinical trials in adults were as follows:

Very Common (may affect more than 1 in 10 people)

- tenderness, pain, warmth, redness, itching, swelling or bruising where the injection is given
- generally feeling unwell
- feeling tired (fatigue)
- chills or feeling feverish
- headache
- feeling sick (nausea)

- joint pain or muscle ache

Common (may affect up to 1 in 10 people)

- a lump at the injection site
- fever
- being sick (vomiting)
- flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills

Uncommon (may affect up to 1 in 100 people)

- feeling dizzy
- decreased appetite
- abdominal pain
- enlarged lymph nodes
- excessive sweating, itchy skin or rash

In clinical trials there were very rare reports of events associated with inflammation of the nervous system, which may cause numbness, pins and needles, and/or loss of feeling. However, it is not confirmed whether these events were due to the vaccine.

In keeping with Public Health England guidance on vaccine associated fever during the pandemic, participants experiencing fever within the first 48 hours of vaccination, with no other primary symptom of COVID-19 (cough, loss of sense of taste or smell) will not be required to self-isolate unless there is otherwise clinical suspicion of COVID-19.

Updated MHRA and JCVI guidance

With any new medicines, side effects are discovered as the medicines are given to more and more people. One which is being investigated as it might be associated with ChAdOx1 nCoV-19 (the vaccine being given to some people in this study) is small blood clots which can occur in different parts of the body including the head.

The overall risk of these blood clots is extremely rare, approximately 4 people in a million. More recently it has been shown that the overall incidence after second doses was 1.3 per million doses, with no reported cases in under 50 year olds. They have advised for the public to be aware of the following side effects in the first 28 days after vaccination:

- Sudden severe or persistent headache that does not improve with pain killers or is getting worse
- An unusual headache which seems worse when lying down or bending over, with changes to your vision, difficulty with speech, muscle weakness or being unusually sleepy
- New and unexplained pinprick bruising or bleeding
- Shortness of breath, chest pain, leg swelling or tummy ache

If you notice any of these symptoms, you should let your parent/guardian know and get immediate advice from a doctor.

What are the good things about taking part?

You are helping us to 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. If you get the Meningitis B vaccine, you will be protected against Meningitis B.

At the end of the study, if the coronavirus vaccine is approved for use in children, we will offer you two doses. 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 prevent coronavirus disease in children. This information may help the vaccine to become available to more children in the future. The results will be in a scientific journal and we will send a letter to you and your parents so you know what we found out.

I want to be part of this study, what should I do?

If you want to take part in this study then let your parents or guardian know and they will get in touch with us.

Thank you for thinking about helping us.