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Participant Information Sheet (12-15 years): Com-COV3

Comparing COVID-19 Vaccine Schedule Combinations in adolescents

"A single-blind, randomised, phase II multi-centre study to determine reactogenicity and immunogenicity of heterologous prime/boost COVID-19 vaccine schedules in adolescents"

Would you like to take part in a COVID-19 vaccine study?

We would like to invite you to take part in our COVID-19 vaccine study. Whether or not you take part is **your** decision. Remember, if you don't want to take part, you should say no (even if your parents want you to be in the study).

If you think you might like to take part, please read this leaflet which explains what the study involves. We will provide another leaflet to your parent/legal guardian, which gives a full description of the study, so that you will be able to discuss it with them. Before making up your mind, ask any questions you want.

Taking part in the study might possibly affect how easy it is for you travel to some countries abroad in the future. There is more information about this in your parent/legal guardian's leaflet, which you can discuss with them.

Why have I been asked to take part?

We are asking you to take part because you are the right age and live in an area where we are doing the study.

What is 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 medicines which are injected to prevent you from becoming unwell from certain diseases. They also help to stop you spreading disease to your friends and family. So, they protect you and those around you.

What is COVID-19?

COVID-19 is a new disease, which since early 2020 has spread around the world. It has caused many deaths and has made many more people seriously unwell.

COVID-19 vaccines that have been shown to work are now being used. They are helping to prevent people from becoming seriously ill or dying from the disease. They also reduce the chance of people spreading the infection to others.

In this country, most adults have now been vaccinated against COVID-19. Older people are much more likely to be seriously ill from COVID-19 than young people. However, children and teenagers do occasionally become very unwell if they catch the disease.

It has recently been decided that all 12- to 17- year-olds in this country should be offered one dose of a COVID-19 vaccine. Immunisation of adolescents against COVID-19 is also occurring in some other countries such as the USA, Australia and Israel, although the age range varies.

What is the purpose of this research study?

The purpose of our study is to find out how well young people (aged 12-16 years) respond to two doses of COVID-19 vaccine. We will compare three different vaccines at different doses.

Our study will look at how your body responds to being given a vaccine. We do this by asking you to fill in a diary where you record any symptoms you may have after the vaccine. If, for example, you have a sore arm, a temperature or a headache, you will record this in the diary. We will also take a blood test each time you visit us. The blood will be sent to a laboratory for special tests which help to show how well your body can resist COVID-19 infection. We measure things in your blood called antibodies and white blood cells, which can tell us if the vaccine has improved your body's ability to resist the infection.

We want to find out if different combinations of vaccines work as well as one another.

We will be using three different vaccines. These are called Pfizer-BioNTech, Moderna and Novavax. The Novavax vaccine is currently only being used in medical studies. Everyone who takes part in the study will be given the same vaccine (Pfizer-BioNTech) for their first dose (which could be given in the study, or may already have been given in the community). They will then be given a second vaccination eight weeks later. There are four different possibilities for this second vaccination. The possibilities are:

1. Another standard dose of Pfizer-BioNTech vaccine
2. A half-standard dose of Pfizer-BioNTech vaccine
3. A half-standard dose of Moderna vaccine
4. A standard dose of Novavax vaccine.

The vaccine you will be given for your second vaccination will be decided by chance. We use something called "randomisation" to do this. You do not have any say in which of the four you will receive. You and your parent/guardian will not be told which vaccine you have been given until later in the study. If you knew, it could make our results less reliable.

Can I take part in the study?

Not everyone can take part. For example, if you have certain health conditions you are not able to participate. This is for safety, and also to make sure that the results we obtain are reliable. Your parent/ legal guardian can fill in a short online questionnaire to see if you would be suitable for this study.

What happens if I do want to take part?

If you decide to take part, we will ask you to visit us up to six times over the period of one year. The visits will be arranged to take place outside of school hours. The visits will take place at the Clinical Vaccinology and Tropical Medicine (CCVTM), Churchill Hospital, Headington.

At the **first visit**, we will make sure you are happy to be in the study. We will answer any questions you want to ask about it. We will ask your parent/legal guardian to sign a consent form and will ask you to sign an assent form.

We will check your temperature, height, weight and briefly examine you to make sure that you are well enough to have the vaccine.

If you are a girl, we will ask you to give us a urine sample to check you are not pregnant. We must do this before giving you a new vaccine (one reason for this is that pregnancy may affect the results of the study). Anyone who could possibly be pregnant (considered to be any female aged 12 and above) must provide a urine sample to check before they receive the vaccination. All female participants who have started their periods must make sure they do not become pregnant while they are in the study.

We will take a blood test. This can sometimes be uncomfortable, but we can give you some cream or spray to help numb your skin first, if you want. Having a blood test can make some people nervous, but it can help if they have something fun to distract them, such as listening to music or reading.

We will be taking samples of fluid from the nose and saliva from some children in this study. You do not have to give these samples, it is up to you. We will discuss what it involves when we see you. If you decide to let us take these samples, we will do so at the first three visits.

We will give you a dose of vaccine (into your arm). Like the blood test, this can also be a bit uncomfortable for a short while.

We will give you a diary to record your symptoms and explain how to use it. We will also give you a thermometer and tape measure. We will want you to record symptoms such as pain, redness or swelling where you had the injection, and also more general symptoms, such as fever, headache or diarrhoea. Not everyone has symptoms after a vaccination.

If you have already had your first dose of a COVID-19 vaccine in the community, at the first visit the study team may only ask you to have a medical check-up and for you and your parent/legal guardian to sign a consent form. Alternatively, we may arrange for both the "first" and "next" visits to happen on the same day.

At the **next visit,** you will have the second dose of vaccine. This will be at about 8 weeks after your first COVID-19 vaccine dose, whether this was given in the community or in our study. We will take a blood test before this second vaccine. For girls, we will check a urine pregnancy test. We will decide which sort of vaccine you will be given for your second dose. This is done in a way that relies on chance. You will not be able to choose the vaccine, nor will your parent/legal guardian.

We will ask you to record your symptoms in the diary after this second dose of vaccine.

At the **rest of the visits**, you will only have a blood test and brief health check. (Saliva and nasal fluid samples will be taken at the third visit if you have agreed to this). These will be

arranged at about 2 weeks, 4 weeks, 4 months and 10 months after your second COVID-19 vaccination.

What if I change my mind?

Taking part in research is entirely **your** choice. You are free to change your mind at any time. You can decide to stop being in the study, even if your parent/legal guardian thinks you should continue.

What are the disadvantages of being in the study?

After the blood test and/or vaccine, your arm may be sore and you may have a bruise.

Vaccines, like all medicines, can sometimes cause unwanted side-effects. Usually these are a minor nuisance (like a sore arm) and they disappear within a few days. Very occasionally the side-effects can be much more serious.

Common side-effects after vaccination include pain, redness and swelling where the injection has been given. Other common side effects include: tiredness; headache; aches in joints and muscles; feeling sick; vomiting.

We now know that the Pfizer-BioNTech and Moderna vaccines can, extremely rarely, cause a serious condition called myocarditis (inflammation of the heart muscle). It seems that this is more likely to occur in boys and young men shortly after their second dose of the vaccine (but, even then, it is very rare).

The Novavax vaccine is currently only used in medical studies. It is not routinely used for the general public. Because it has been used in fewer people, we know less about the very rare side-effects it might cause than we do about the Pfizer-BioNTech and Moderna vaccines.

What are the advantages of being in the study?

In this country healthy young people aged 12 to 17 years are advised to receive a single dose of a COVID-19 vaccine, but are not offered a second dose of vaccine (unless they live with someone who is at increased risk from COVID-19). By taking part in this study, you would receive two doses of COVID-19 vaccine. This is likely to mean that you are better protected against the disease than if you were unvaccinated. You may also be less likely to pass the infection on to people around you. However, you should remember that vaccination doesn't guarantee that you will be protected from COVID-19; you should continue to take care to protect yourself.

By taking part in this study, you would be helping us to learn more about which vaccine combinations work best in young people. The results might help to guide future decisions about how best to use vaccines in children and young adults.

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

If you want to take part in this study, then let your parent/legal guardian know and they will get in touch with us.

Remember that taking part in the study is up to you. Even if your parents want you to take part, you can say no if you don't want to be in the study.

Thank you for thinking about helping us.