OXFORD VACCINE GROUP

A Study Exploring Whooping Cough Protection in Children and Adults

Study Information Booklet (11-15yrs)

You are invited to take part in a study looking at how your body responds to a pertussis (whooping cough) vaccine.

The study is being run by the Oxford Vaccine Group and will involve healthy children, teenagers and adults.

Before you decide whether to take part, it is important for you to understand what the study is about and what it would involve. Please take the time to read the information carefully, and discuss it with your parents. If anything is unclear or you would like more information please contact the study team.

Thank you for taking the time to think about being part of the study.

What is the Oxford Vaccine Group?

The Oxford Vaccine Group is part of the University of Oxford. We are an independent team of doctors, nurses and play assistants (the study team). We carry out research studies of new and improved vaccines for babies, young children, teenagers and adults.

A research study is where you look at something like a vaccine or a disease and try to understand more about it. In the past 5 years alone, over 7000 people in this area have taken part in our research studies.

Why have I been invited to take part?

You have been invited because you were born in a year where you are likely to have been vaccinated against pertussis (whooping cough) and are at the age that we are targeting for our study.

You also live in an area where the study is being carried out.

What are vaccines?

Vaccines are a type of medicine that can help to stop you from becoming ill. They work by helping your body to fight germs that cause infections that can make you unwell. Vaccines are usually given as injections in your arm. Without vaccines, people are at increased risk of catching many serious diseases.

What is pertussis and whooping cough?

Pertussis, most commonly known as 'whooping cough', is caused by a germ that is a bacteria that affects the lungs. It can be life-threatening and mostly affects babies, young children and those who have not yet had the vaccines.

At your age, if you are infected with these bacteria it usually causes symptoms such as a runny nose and cough that can last for 1-2 weeks. In younger children sometimes the infection can become more serious. It can cause severe

coughing which can lead to vomiting and difficulty with breathing. These symptoms can last for up to 3 months. People can carry the bacteria even if they do not have any symptoms, and the infection can spread easily from person to person when they cough or sneeze.

What do we want to do in this study?

There are two different types of whooping cough vaccines available in the world, known as 'acellular' and 'whole-cell'.

The whole-cell vaccine was the first vaccine for whooping cough to be available in the world and was introduced into the UK routine schedule in 1957. The UK switched from using the whole-cell vaccine to the acellular in 2004 due to high temperatures, redness and swelling at the site of injection being more common in people given the whole-cell vaccine than in those given the acellular vaccine.

In this country, a high number of children are vaccinated against whooping cough, but some children still become ill from the bacteria.

We, the study team, will give those children in the study a dose of acellular vaccine. This will help us understand how well the vaccine works and the effect of previous doses of whooping cough vaccines that those children were given when they were much younger.

What vaccine will be used in the study?

The vaccine is called Boostrix®IPV. It is usually given to children before they start school. It protects against three other diseases (or 'germs') (diphtheria, polio and tetanus) as well as whooping cough. The whooping cough part of the vaccine is acellular.

What would happen to me?

Over the next year the study team would visit you at your home four times in total. You would be given the vaccine in your arm once the first time we see you. The study team would stay for at least 15 minutes after giving you the vaccine, in order to check the place where the vaccine was given and ask about any changes in how you feel.

To help us understand how well the vaccine is working we need to take a small amount of blood four times during the study period. This will happen at the first visit and then at the following three visits. Each time the study team would take a maximum of 26ml of blood (approximately 5 teaspoons). A maximum of 102ml of blood will be taken over the one year study.

We would use a cream to numb the skin on your arm, which should help to make it more comfortable. Listening to music or reading can help to distract you from a blood test.

During the first visit we would measure your temperature. You and your parents would be asked questions about your health.

Females only

It is important that we make sure no one is pregnant during the study. If you are female and you have already had your first period, the doctor or nurse will need to ask if there is any possibility you may be pregnant before receiving the vaccine. Should it be appropriate your parent/guardian will be present during this conversation. If there is a possibility you are pregnant, we would not be able to give you the vaccine or be able to continue in the study and we would need to inform your GP.

What are the possible risks/side effects of taking part in this study?

The possible risks and discomforts of receiving the Boostrix®IPV vaccine are detailed below.

Very common at the injection site (affecting more than 1 in 10 people):

- pain
- swelling
- redness

Rare general effects not at injection site:

- headache
- sickness (nausea)
- painful muscles and joints
- generally feeling unwell

Some people have reported allergic reactions (sometimes severe) but this is rare. An immediate severe allergic reaction (anaphylaxis) can result in a rash, swelling of the body and breathing difficulties. The study team would observe you for 15 minutes following the vaccination as this is the time most reactions are expected to happen. The study team members carry adrenaline (medicine to treat anaphylactic reactions) and are trained to administer it should such a reaction occur.

You would be checked for side effects mentioned throughout your study participation. Sometimes there can also be a bruise where the blood was taken. You may feel faint or light-headed for a while, but this will go away if you lie down for a few minutes. There is also the possibility of fainting after blood sampling.

You must tell your parents or guardian and the study team if you feel unwell at any time.

What are the good things about taking part?

You would benefit from taking part in this study by receiving a vaccine that is not currently given to children and teenagers at your age and which should increase your protection against whooping cough, and other diseases (diphtheria, tetanus and polio). The vaccine will also be administered at your home.

Who else would know I am taking part in the study or see information about me?

Your parents, your doctors and the study team would know that you are taking part. The study team will know your name, address and date of birth, and if you have ever been ill enough to see a doctor. This information will be stored in a locked cupboard and only shared with people to make sure the study team are doing their jobs correctly.

No one else would know unless you want to tell them. Your name and your address will not be given to anyone, and to make sure of this we would use a special code (a "study number") for all the information collected about you. We would need to access your medical history in order to see what vaccines you were given as a child.

What will happen to my blood samples?

Your blood samples will only be identified by a study number and stored within a library of samples that's called a 'Biobank' in order for us to use to answer our questions about whooping cough. We may share your blood samples with other researchers who also want to know more about whooping cough but will not share any details about you.

Do I have to take part?

You do not have to take part in this study if you don't want to. It is important to talk to your parents. If you have any questions you should ask your parents or the study team who can answer all your questions. You can take your time to decide and even if your parents want you to be in the study you can still say no. If you do say yes, you can change your mind at any time and leave the study. It is your decision.

If you are unhappy with anything related to this study, you can tell your parents or the study team.

What do I do now?

Talk to your parents about taking part. If you decide you would like to take part, ask your parents to speak to the study team.

Thank you for thinking about the study,

Whooping Cough Study Team

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Assent Form 11 - 15 year olds

To be completed at the first visit: please circle 'yes' if you agree with what is written, or 'no' if you do not agree

I have read about this research study	**Yes/No**
I understand what the study is about	**Yes/No**
I have asked any questions that I want to and understood the answers that I was given	**Yes/No**
I have had time to think about taking part	**Yes/No**
I am happy for my medical notes to be looked at by the study team or other people and they will keep my information private	**Yes/No**
I understand that I can change my mind about taking part at any time, even if my parents would like me to take part	**Yes/No**
I understand that 4 blood samples need to be taken for the study	**Yes/No**
I understand that I will have 1 vaccine in the study	**Yes/No**
I am happy to take part in this study	**Yes/No**
15 year olds only:	
I am aware that if I turn 16 years old whilst in this study I will need to complete a new consent form to say that I am still happy to take part in this study	**Yes/No/NA**
Girls only:	
I understand that if I have started my periods, I will be asked if I maybe pregnant	**Yes/No/NA**

Participant Name: …… Signature: …… Date: |___ ___| |___ ___| |___ ___|
Study Nurse/Doctor Name: …… Signature: …… Date: |___ ___| |___ ___| |___ ___|

Top copy retained at OVG site and bottom copy to participant

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