

Participant Information Sheet

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| **Study Title:** | OPTIMUM |
| **Protocol number** | Version X.X, XX.XX.XX |
| **Study Sponsor:** | St George’s, University of London  |
| **REC reference**  | 19/YH/0050 |
| **IRAS number** | 249236 |

**Why is this study being performed?**

The whooping cough vaccine (Boostrix-IPV®- a combined vaccine of whooping cough, diphtheria, tetanus and polio) has been offered to all pregnant women in the UK since 2012 to provide protection for the baby against whooping cough in the first few months of life. We do not yet know the best time to give this vaccine in pregnancy to provide maximum protection for babies. This study is designed to address this question.

In this study we will randomise women (i.e. “toss of a coin”) to receive the vaccine in one of three time periods, all of which are within the UK recommendations, to see if there is a difference in the antibody levels in infants. Antibodies are the proteins in the blood that provide protection against infections. We are also very interested in the immunity in breastmilk following whooping cough vaccination in pregnancy and if you decide to breastfeed you can decide to take part in an additional sub-study investigating breastmilk immunity following vaccination in pregnancy. This is not part of the main study and you do not have to take part in this even if you decide to breastfeed.

The results of this study will help inform vaccination strategy in the UK and worldwide.

**Why have I been chosen and do I have to take part?**

You have been approached about this study because you are pregnant and have not yet received your whooping cough vaccine. You do not have to take part in the study and if you do choose to take part you would be able to withdraw from the study at any time and without giving a reason. If you do not wish to take part in this study or you choose to take part and then decide to withdraw from the study before the end, your care will not be affected in any way.

**What happens if I take part?**

Participation will involve four (or six if you are taking part in the sub-study investigating immunity in breastmilk) study visits for you and one for your baby. One or two of the study visits may coincide with routine hospital attendance.

**Study visits**

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| **Visit Number** | **Maternal visit 1** | **Maternal visit 2** | **Maternal visit 3** | **Maternal visit 4** |  **Breastfeeding visit 1\*** | **Breastfeeding visit 2\*** | **Infant 1** |
| **Timing** | At or before 23+6 weeks | At time of vaccination (according to group) | Vaccination+14 days (+/- 2) | Delivery |  <48 hours from delivery | Delivery+14 days (+/- 2) | 28-42 days following third whooping cough vaccination |
| **Activity** | Screening & enrolment | Maternal blood sampling and vaccination. Diary card provided. | Maternal blood sampling. Diary card collected. | Maternal blood and cord blood sampling | Colostrum sampling | Collection of breast milk sample | Infant blood samplingCollection of breast milk sample if still breastfeeding |

\*For women participating in the optional breastfeeding sub-study

**Maternal study visit 1**

If you choose to take part, we will arrange a convenient time for you to come to LOCAL INSTITUTION NAME for a study visit. This first visit can be performed on the same day that you have received this information sheet if you wish. At this visit we will discuss the study with you and will ask you to sign a consent form. After this we will collect some details about your general health, vaccine history and your pregnancy and you will be randomly assigned to receive the whooping cough vaccine in one of three time periods: ≤23+6, 24-27+6 or 28-31+6 gestational weeks. If you are randomised to the group receiving the vaccination at ≤23+6 gestational weeks your vaccination visit can take place on the same day as your first study visit if this is convenient for you. Otherwise, we will arrange a suitable time for you to come for your vaccination visit.

**Maternal study visit 2**

At your second visit you will have a blood sample taken to allow us to measure the levels of antibodies before you have received your vaccine. This blood sample will be about 7.5mls in volume (about one and a half teaspoons) and will be taken by an experienced member of the research team. After this blood test you will receive your whooping cough vaccine. Following this we will ask you to remain with us for 20 minutes for observation and during this time we will provide you with a diary to be completed over the following 7 days and we will explain to you how this should be completed.

**Maternal study visit 3**

The next study visit will be 14 days after your vaccination when we will collect the diary card, enquire about your health since your vaccination and take another blood sample so that we can measure the levels of antibodies after your vaccination.

**Maternal study visit 4**

After your baby’s birth we will take a sample of cord blood to measure the level of antibodies in the cord blood at birth. This involves taking a sample of blood from the cord after the cord has been clamped and cut. This does not hurt you or your baby. Taking a cord blood sample will not affect any requests for delayed cord clamping and will not impact on your ability to bank cord blood if that is something you wish to do. In the unlikely event that we are unable to obtain a cord blood sample we will ask if we can take a blood sample from your baby before they are seven days old. We will also take a blood sample from you to measure the levels of antibodies several months after your vaccination.

**Breastmilk visit 1 (OPTIONAL)**

If you decide to breastfeed your baby and have consented to take part in the sub-study investigating immunity in breastmilk after vaccination we will arrange to see you within 48 hours of your baby’s birth to collect a sample of around 1-2 mls of colostrum. We will be able to provide advice about how to obtain this sample and we will collect this sample immediately following a feed.

**Breastmilk visit 2 (OPTIONAL)**

If you are taking part in the sub-study investigating immunity in breastmilk after vaccination and are still breastfeeding at 14 days we will ask you to provide a sample of around 2-5 mls of breastmilk. We will arrange to collect this from you.

**Infant visit 1**

The final study visit will take place 4-6 weeks after your baby’s third set of vaccinations, at around 5 months of age [IF LOCALLY APPLICABLE: and can take place in your home if you wish]. We will be in contact when your baby is around two months old to check that your baby’s vaccinations have started and again when your baby is around 4 months old to arrange the appointment. At this visit we will ask you some questions about your baby’s health and will take a blood sample to measure the levels of antibodies in your baby. This blood sample will be about 3-5mls in volume (no more than a teaspoon) and will be taken by an experienced member of the research team. It is routine practice to use a medicated numbing cream to numb the area prior to blood collection and you will be offered this for your baby. If you are taking part in the sub-study investigating immunity in breastmilk after vaccination and are still breastfeeding at the time of this visit we will also collect a sample of around 2-5 mls of breastmilk.

If you attend INSERT LOCAL INSTITUTION NAME for any of your study visits your travel expenses can be reimbursed.

**What are the possible disadvantages of taking part?**

This study involves three blood tests from you and one blood test from your baby(or two if cord blood not collected) as well as a sample of colostrum and up to two samples of breastmilk if you take part in the breastfeeding sub-study. Blood tests can be uncomfortable, but these will be performed by an experienced member of the team and you will be offered a medicated numbing cream for your baby. There will be 4 (or 6 if you take part in the breastfeeding sub-study) study visits although the first and possibly the second of these can be conducted alongside routine hospital attendance [IF LOCALLY APPLICABLE: and the infant visit can be performed in your home]. The visit to collect the sample of colostrum will take place in hospital or at home and we will come to your home to collect the sample of breastmilk at 14 days. We will try to arrange the study visit at a time convenient to you.

**What are the possible benefits of taking part?**

You would be helping us to understand more about the impact of timing of the whooping cough vaccination in pregnancy on the protection transferred to the infant. This research will inform decisions about the timing of vaccination in the UK and worldwide.

**What happens when the research stops or if new information becomes available?**

If new or relevant information becomes available during the course of the study, we will inform you as soon as possible.

**What if there is a problem?**

St George’s, University of London is the study sponsor and is covered by appropriate indemnity. If you are harmed as a result of your participation in the study, you may be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received as part of the study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. These arrangements do not affect your right to pursue a claim through legal action. Where the Trial is conducted in a NHS hospital, the NHS has a duty of care to participants.

**What if you wish to make a complaint about the trial?**

If you have any concerns about the way you have been treated during this study or wish to make a complaint, then you can talk to the OpTIMUM research team who will do their best to answer your questions or concerns (contact details at the end).  Alternatively, you may contact the Patient Advice and Liaison Service:

[INSERT LOCAL PALS DETAILS]

The National Health Service complaints mechanisms are also available to you.

**How will my personal data be handled?**

St George’s, University of London (SGUL) is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records, and that of your child in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. We may keep information collected for the purpose of the study for up to 5 years after the study has finished. This is to ensure integrity of the results. All data will be stored in a secure manner.

[SITE NAME] will collect information from you and/or your medical records, and that of your child for this research study in accordance with our instructions.

[SITE NAME] will keep identifying information confidential and will not pass this information to SGUL. [SITE NAME] will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from SGUL, [SITE NAME] and regulatory organisations may look at your medical and research records to check the accuracy of the research study. SGUL, as sponsor, will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, identifying information or contact details.

[SITE NAME] will keep identifiable information about you from this study for up to 3 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your research information in specific ways in order for the research to be reliable and accurate. If you withdraw your consent to participate in a research project, this will not mean we will have to remove all data as well. We will keep the information about you that we have already obtained to ensure research integrity is maintained in the public’s interest.

You can find out more about how we use your information here:

<https://www.sgul.ac.uk/privacy>

For general information on how the NHS uses research data please visit: <https://www.hra.nhs.uk/information-about-patients/>

**What would happen to any samples?**

Your blood samples will be sent to the Public Health England laboratory at Porton Down to be processed, analysed and stored. If you are taking part in the sub-study investigating immunity in breastmilk after vaccination the samples of colostrum and breastmilk would be processed, analysed and stored at St George’s, University of London. If you have given consent for us to retain any leftover samples, these would be stored at the Public Health England laboratory at Porton Down, St George’s, University of London or another approved laboratory and could be used for other ethically approved research.

**What would happen to the results of the research study?**

Your local study team will write to you at the end of the study to inform you of the study findings. This will be around 12 months after the end of the study. This may be some time after your participation in the study has ended. We will retain your contact details in a secure database at the site to enable us to contact you. We plan to publish the results in a medical journal so that other healthcare professionals can learn about the findings of the study. If you wish, you can also be sent a copy of the published research.

**Who is organising and funding the research?**

The study is funded by the Al Thrasher Research Fund and the UK Department of Health. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect the interests of donors/participants. This study has been reviewed and given favourable opinion by Yorkshire and the Humber- Bradford/leeds Research Ethics Committee, as well as approval by the Health Research Authority and St George’s Joint Research and Enterprise Service.

**Further information**

If you have any questions, or would like further information please contact:

 [INSERT LOCAL CONTACT DETAILS HERE]

We do hope that you will take part in this study. Your contribution would allow us to understand more about how the whooping cough vaccine can be used in pregnancy to provide the best protection to infants.

**Thank you for reading this information and thinking about taking part in the study.**