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**A human controlled infection study to establish a safe, reproducible and practical human *Bordetella pertussis* colonisation model for the identification of correlates of protection against colonisation.**

Volunteer information sheet – Phase A

We would like to invite you to take part in a research study. Before making a decision about whether or not to take part, please take the time to read this information sheet and discuss it with friends, relatives and your General Practitioner (GP) if you wish. One of our study team will go through the information sheet with you and answer any questions you may have.

### In summary

In this study, we are trying to find out how we can best protect people against the disease **Whooping Cough** and stop it spreading from person to person. To do this, we will be performing a deliberate controlled infection of the nose, so that the body is transiently infected with the agent that causes this disease.

You do NOT have to take part. Before you join we will explain in the following pages exactly what it entails (the procedures, investigations, time commitment and a short balanced presentation on risk and benefits) but **first we want to highlight key points** that we think you should know before making a decision. If you are still interested in joining our study, we'll then get into more detail.

- You'll be given a small dose of live bacteria into your nose
- You'll be admitted in the research unit for 17 days and have investigations to measure the course of the infection and your immune response to it
- There is a small chance you will get the symptoms of whooping cough but we will closely monitor you and treat early
- You mustn't have had any past problems with your immune system
- We must confirm eligibility through your GP

If you are interested, the following pages will explain more about the study.

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## What is *Bordetella pertussis*?

Whooping cough, also called pertussis, is a bacterial infection of the lungs and airways. It is caused by a bacterium called *Bordetella pertussis* (*B. pertussis*). Whooping cough can cause repeated coughing bouts that can last for two to three months or more. Young babies under six months of age are typically affected and are in the age group that is most vulnerable to serious complications. In older children and adults it tends to be less serious, although it can still be unpleasant and frustrating. In some adults who are infected there may be no symptoms at all, so that the infection passes unnoticed. *B. pertussis* is spread in the droplets produced when someone with the infection coughs or sneezes. Therefore you can catch whooping cough if you come into close contact with someone with the infection. The first symptoms are similar to those of a cold, such as a runny nose, red and watery eyes, a sore throat, and a slightly raised temperature. Intense coughing bouts typically start about a week later. Antibiotics will help stop the infection spreading to others, and usually (*but do not always*) reduce the symptoms. If antibiotics are given during the early phase of the infection, it is believed that the cough can be prevented, but there are exceptions to this rule and it is possible that people who are given antibiotics even during the early phase of illness may go on to develop the cough. Although a pertussis vaccine is offered to all babies in the UK, the vaccine does not offer lifelong protection. In fact, protection by the vaccine seems to be less nowadays in comparison to 15 years ago.

## What is the purpose of this study?

This study is part of a project that aims to develop a better vaccine against whooping cough. To do this we need to know more about the immune response generated against *B. pertussis* and what kind of immune response protects against whooping cough. This study is designed to look at those particular questions by inoculating healthy volunteers with nose drops containing *B. pertussis*, then monitoring their immune response before giving them an antibiotic to clear *B. pertussis*.

Previous studies, which have been performed with an attenuated ('weakened') live *B. pertussis* have shown that giving nose drops can result in colonisation – when the bacteria live in the nose and throat of the volunteer without causing any disease. In these previous studies, those volunteers who were successfully colonised were seen to produce an immune (antibody) response to the bacteria, in a similar way to producing an immune response after a vaccination. This has never been done with non-attenuated *B. pertussis* before.

In this study we are aiming to cause colonisation with *B. pertussis* and analyse the immune response triggered by this colonisation, without causing the volunteers to become unwell. The study is comprised of two phases. In phase A we will give nasal drops with *B. pertussis* at a low dose of bacteria, with the aim of achieving colonisation in most, but not all, volunteers. If that dose works, then all subsequent volunteers will receive the same dose. If it doesn't work then subsequent volunteers will receive progressively higher doses until colonisation is reproducibly achieved. If we find the dose is too high in initial volunteers (because it results in colonisation in all of them) the subsequent volunteers will receive a lower dose. In phase B we will give the optimised dose of nose drops to 30 healthy volunteers and a sham inoculum (salty water only, with no bacteria) to 15 volunteers.

All volunteers in Phase A who have been inoculated with *B. pertussis* will be admitted to the NIHR Wellcome Trust Clinical Research Facility at University Hospital Southampton for a maximum of 17 days.

## Am I eligible to take part?

In order to be involved in this study you must be:

- A healthy adult aged 18 to 45 years inclusive on the day of screening
- Fully conversant in the English language
- Able to communicate easily by both mobile telephone and text messaging
- Able and willing (in the investigator's opinion) to comply with all study requirements
- Willing to give written informed consent to participate in the trial
- Willing to take a curative antibiotic regimen after inoculation with *B. pertussis* according to the study protocol
- Willing to be admitted to the NIHR-WTCRF Southampton for 17 days for phase A (from inoculation until two days after the eradication therapy is given) and for the duration necessary for phase B (maximum of 17 days; dependant on phase A results)
- Able to answer all questions on the informed consent quiz correctly

Acceptable forms of contraception include:

- Established use of oral, injected or implanted hormonal methods of contraception
- Placement of an intrauterine device or intrauterine system
- Total hysterectomy
- Barrier methods of contraception (condom or occlusive cap with spermicide)
- Male sterilisation if the vasectomised partner is your only partner
- True abstinence when this is in line with your preferred and usual lifestyle

You cannot participate in this study if:

- You have inviolable commitments within 3 months of discharge from the inpatient phase of the study to make contact with:
  - unimmunised or partially immunised children and infants aged < 1 year
  - pregnant women >32 weeks who have not received pertussis vaccination at least a week prior to contact
- You have household contacts working with
  - unimmunised or partially immunised children and infants aged < 1 year
  - pregnant women >32 weeks who have not received pertussis vaccination at least a week prior to contact
- Phase A only: You have had recent *B. pertussis* infection
- *B. pertussis* is detected on nasopharyngeal swab taken before the challenge

- You have signs of a current infection at the time of inoculation with *B. pertussis*
- You have participated in other interventional clinical trials in the last 12 weeks
- You have a history of receiving *B. pertussis* vaccination in the last 5 years
- You are a current smoker
- You have received systemic antibiotics within 30 days prior to the challenge or plan to during the study period
- You have a confirmed or suspected immunosuppressive or immune-deficient state, including HIV infection; asplenia; recurrent, severe infections and chronic (more than 14 days) immunosuppressant medication within the past 6 months (inhaled and topical steroids are allowed)
- You have received immunoglobulins or blood products within the 3 months prior to enrolment
- You have a history of allergic disease or reactions likely to be exacerbated by any component of the inoculum
- You are not allowed to use azithromycin or macrolides for medical reasons
- You are pregnant, breast-feeding or are planning to become pregnant during the study
- You have any clinically significant abnormal finding on screening investigations or clinical examination - in the event of abnormal test results, confirmatory repeat tests will be requested
- You have any other significant disease, disorder, or characteristic which in the opinion of the investigator, may (i) significantly increase the risk to you if you participate in the study, (ii) affect your ability to participate in the study or (iii) impair interpretation of the study data. Examples include recent surgery to the nasopharynx, or evidence of recreational drug use.

If you have private medical or travel insurance you are advised to contact your insurance company before participating in this trial, because involvement in this study may affect the cover provided by private insurance.

### Do I have to take part?

No. It is up to you to decide whether or not to take part. If you are interested in taking part, a member of the study team will discuss the study with you and answer any questions you may have. You will then be asked to sign a consent form. You are free to withdraw from the study at any time without giving a reason, but you may be asked to come to a follow up visit for safety reasons.

### What will happen if I take part?

This study involves a nasal inoculation and a period of admission to the NIHR Wellcome Trust Clinical Research Facility at University Hospital Southampton.

Volunteers in phase A will all receive nasal inoculation with *B. pertussis* and will be admitted to the for 17 days followed by 4 follow up visits. At the moment we are only looking for volunteers for phase A.

The study timetable for phase A is summarised in the tables below:

Table 1: Visits and procedures phase A

Day	-30	-7	0	2	3	4	5	7	9	11	14	15	16	28	56	183	365
Visit	x	x												x	x	x	x
Admission																	
Inoculum			x														
Bloods	x	x	x	x	x	x	x	x	x	x	x			x	x	x	x
Urine	x		x														
ECG	x																
Nasal wash		x				x		x	x	x	x		x	x	x	x	x
Nasal fluid sample		x				x		x	x	x	x	x	x	x	x	x	x
Nasopharyngeal swab	x	x			x		x	x	x	x	x	x	x	x			
Throat swab		x			x		x	x	x	x	x	x	x				
Saliva		x			x		x	x	x	x	x	x	x				
Antibiotic therapy											x	x	x				

In phase B the volunteers will be split into two groups. Group 1 will receive nasal inoculation with *B. pertussis* and will be admitted for approximately seven days (depending on Phase A results) followed by five follow up visits. Group 2 will receive a sham inoculum (salty water with no bacteria present). Persons in Group 2 will not be admitted but will come to the unit for six follow up visits. You may be able to choose which group you are in as long as there are places available.

### Screening visit

If you are interested in taking part in this study you will be invited to attend a screening appointment at the NIHR-Wellcome Trust Clinical Research Facility at University Hospital Southampton. This will take place up to 30 days prior to inoculation and will last up to one hour. The purpose of this visit is for us to discuss the trial with you and for you to decide if you wish to participate. You will be asked to fill in a questionnaire to make sure that you fully understand the study. You will be shown where you will be admitted if you decide to participate and are eligible. If you decide to participate then you will be asked to sign a consent form. We then need to check that you do not have any health conditions that affect your eligibility for the study or make the study unsafe for you. A doctor will ask you some medical questions and examine you. We will ask you to fill in the General Health Questionnaire to screen for personality or psychiatric disorders. We will take a nasopharyngeal swab, take a blood sample, make an ECG (heart-tracing) and do a urine test (including a pregnancy test for females). We will send a letter to your GP asking to confirm your medical history to make sure this study is safe for you and we will provide them with information about what the study involves.

### Pre-inoculation visit

If you are eligible for the study, we will ask you to come for a pre-inoculation visit 7 days before inoculation to check that you are still not carrying natural *B. pertussis* and take some base line samples. Once this is confirmed you will be asked to return on the day of the inoculation for admission to the research unit.

## Inoculation day

We will ask you not to eat or drink anything other than water for the hour prior to your inoculation. We will check that you are still happy to continue in the study and that nothing has changed with your medical history. Prior to the inoculation we will take some blood tests. Females will also have another pregnancy test.

You will then be given the inoculation of *B. pertussis*. You will be asked to lie on your back with your neck extended back and 0.5ml of fluid containing a carefully measured amount of bacteria will be dripped slowly into each nostril over approximately 1 minute for each nostril. You will be able to breathe through your mouth during this procedure. Following the inoculation you will be asked to remain lying down for 5 minutes and then you will be observed for a total of 15 minutes.

## Admission to the research facility

Immediately following the inoculation, volunteers who have been inoculated with *B. pertussis* will be admitted to the research unit. Volunteers in phase A will be admitted for 17 days. During admission you will have frequent reviews by the study doctors and nurses and regular nasal and blood samples will be taken to look for successful colonisation and an immune response. The shedding of *B. pertussis* be assessed daily after challenge using analyses of the face mask you are wearing, sampling the air in your bedroom, taking samples from surfaces in the room, dipping your fingertips in a small dish with water and by letting you cough/talk inside a coughbox. This coughbox is like a glass cupboard which you can sit in while we take air samples.

## Eradication and discharge

Prior to discharge you will be given a three day course of an antibiotic called azithromycin to clear colonisation of *B. pertussis* from your nose and throat. We will check that *B. pertussis* has been successfully cleared by performing a nasopharyngeal swab 24 and 48 hours after eradication. In phase A this treatment will be given on days 14, 15 and 16. If we suspect that you are developing whooping cough then we will start treatment immediately and will discharge you after the last dose of antibiotics.

## Follow up visits

Participants will be asked to return on Day 28, 56, 183 and Day 365 after inoculation for follow up visits. We will repeat the nasal and throat samples and also take some blood tests, to look for an immune response to *B. pertussis*.

## Investigations:

### Nasopharyngeal swabs

This test involves passing a cotton wool swab on a stick into your nose so that it touches the back of your throat. This can feel a little uncomfortable, but not painful, and may lead to a sensation of gagging which lasts no more than a couple of seconds.

### Nasal fluid samples

We collect nasal fluid in two different ways. Firstly we will use a small piece of filter paper, which is placed on the inside of your nostril and left for 5 minutes. After this

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time it will have collected a small amount of fluid, which we will analyse in the laboratory. Secondly we will perform a nasal wash, which will involve warm salty water being instilled from a syringe into each nostril, 5 ml (1 teaspoon) at a time. We will then ask you to tip your head forward to let the fluid back out and collect it for analysis.

### Throat swabs

This test involves passing a cotton wool swab on a stick into throat so that it touches the back of your throat. This can feel a little uncomfortable, but not painful, and may lead to a sensation of gagging which lasts no more than a couple of seconds.

### Saliva samples

This test involves rubbing small sponge on a stick on the inside of your mouth for about 25 seconds. This can feel a little uncomfortable, but not painful.

### Environmental samples

Environmental samples that will be collected include sampling the air in your bedroom, taking samples from surfaces in the room, dipping your fingertips in a small dish with water and coughing/talking inside a coughbox. This is not considered to be uncomfortable.

## Where will I be staying?

To prevent infecting other people, especially vulnerable people, with *B. pertussis* volunteers will be admitted to a dedicated area of the NIHR Wellcome Trust Clinical Research Facility which is located on C level of University Hospital Southampton. While admitted, volunteers will have access to dedicated rooms, toilets, shower and a recreational area. Volunteers will be able to leave the designated area during daytime for a maximum of two hours two times a day, providing that they follow the necessary infection prevention measures. They will be required to stay inside from 18.00 till 8.00 and meals, drinks, snacks and entertainment will be provided.

To protect you from developing illness outside the research unit and to prevent possible cross infection of other people the volunteer will have to adhere to the following rules:

1. You are only allowed to leave the NIHR-WTCRF with the permission of the clinical team during admission and are allowed to leave the designated area during daytime for a maximum of two hours twice a day.
2. When you leave your personal room the isolation area at the NIHR-WTCRF unit you will have to wear a surgical mask to cover your nose and mouth.
3. When you are in the recreational room you will have to wear a surgical mask to cover your nose and mouth
4. You are not to enter the room of other admitted volunteers
5. Starting at inoculation until 3 months after discharge you are not allowed have contact with
  - a. healthcare workers working with one of the groups mentioned below
  - b. unimmunised or partially immunised children and infants aged < 1 year.

- c. pregnant women >32 weeks who have not received pertussis vaccination at least a week prior to contact
6. You need to wash your hands before leaving your room and are not allowed to have direct face-to-face contact (< 2 metre distance) for greater than a cumulative period of 1 hour with other people during the admission period.
7. You are not allowed to have any direct contact that could involve transfer of respiratory secretions to anyone during the admission period.
8. When you leave the unit you must be carrying a mobile phone with the study emergency phone number programmed in, and contact the clinical study team if necessary.
9. You must be able to be return in the NIHR-WTCRF within 30 minutes.
10. You will have to be contactable by telephone while outside the NIHR-WTCRF.
11. You may receive a maximum of two guests at a time between 8.00 and 22.00, who must wear masks covering nose and mouth while in close proximity to you and must adhere to strict infection control procedures.

## What are the risks of taking part?

### Blood tests

The maximum total volume of blood taken during the study is approximately 580 ml over a year. The amount taken on one day will be a maximum of 65 ml (13 teaspoons). The volume of blood being taken over the course of the trial should not cause any problems in healthy people. There may be some temporary mild discomfort, such as bruising and tenderness at the site where the blood tests are taken. You may experience faintness as a result of the blood test. We will give you a copy of your blood test results if you request them, and will only send the results to your GP if you wish us to and will not report them to anyone else without your permission.

### Nasopharyngeal swabs, throat swabs, saliva samples and nasal fluid samples

These procedures can be a little uncomfortable or cause gagging but this will resolve quickly and should not be painful or pose any risk to you.

### Inoculation

The inoculation with fluid containing *B. pertussis* may cause some irritation of the nose that will disappear within a few seconds.

### Whooping cough

Although the aim of the challenge model is to establish colonisation of *B. pertussis*, but not to cause whooping cough, **there is a possibility that whooping cough may occur as a result of the inoculation.**

Initial symptoms of whooping cough in adults include a runny nose, sneezing and 'flu like symptoms, hoarseness, sinus pain, headaches and a persistent cough. If you have one or more of these symptoms we will review you immediately. If we suspect

you are having a normal cold we will keep an extra close watch on you for the next 48 hours and take extra safety blood tests . If we suspect that you are developing whooping cough then we will start treatment immediately. We expect such early treatment to reduce the illness in comparison to natural infection where treatment is often delayed due to the typically mild and non-specific presentation. However there are always exceptions to every rule and we cannot exclude the possibility that you may be left with a lengthy cough as a result of taking part in the project.

In adults who develop whooping cough, coughing episodes may disturb sleep or result in vomiting, and occasionally cause whooping. Adults can develop complications from pertussis, but they occur less frequently and are usually less severe than in children. Reported complications of pertussis disease include urinary incontinence (during the coughing bouts) , rib fractures, collapsed lungs, inguinal hernias, aspiration, pneumonia, seizures and ear infections. These complications have only been reported in children, or in debilitated adults who suffer from other diseases or who are older than 65 years.

## Eradication

An antibiotic called azithromycin will be used to eradicate *B. pertussis* colonisation at the end of the experimental colonisation period. It is a licenced drug in the UK for the treatment of pertussis, and the treatment consists of a dose of 500 mg once daily for three days. We will need to watch you taking the doses.

Azithromycin is generally well tolerated, but may occasionally cause some side effects. The side effects include:

Common: Abdominal discomfort; diarrhoea; nausea; vomiting

Uncommon: Jaundice; liver dysfunction; rash

Rare: Antibiotic-associated colitis; heart rhythm problems; pancreatitis; Stevens-Johnson syndrome; toxic epidermal necrolysis (serious skin conditions)

Frequency not known: Reversible hearing loss (sometimes with tinnitus) can occur after large doses

If you experience any of these symptoms you should contact a doctor immediately, and then inform us.

Azithromycin does not interfere with the contraceptive pill.

## Are there any benefits to taking part?

It is possible that taking part in this study will result in you having a degree of immunity to whooping cough but we cannot be certain that you will benefit directly from this study. We hope that the information gained from this study will help inform the development of vaccines to prevent pertussis and the associated serious complications in the future. You may gain some general information about your health as part of this study. If abnormal results or undiagnosed conditions are found in the course of the study these will be discussed with you and your GP will be informed. For example, a new diagnosis of anaemia or a psychological disorder might be made. Any newly diagnosed conditions will be looked after by your GP within the NHS.

## Will my taking part in this study be kept confidential?

Yes, all information that we collect about you will be coded with a study number and kept confidential. The information will be available to the study team, safety monitors, sponsor, government regulatory agencies and external monitors who can ask to audit or monitor the study. All study information will be held in paper form in a locked room in the NIHR-Wellcome Trust Clinical Research facility or in electronic form on a secure server. Any information that leaves the hospital will have sufficient information removed so that you cannot be identified.

## What will happen to the results of the research study?

We intend to publish the results of this study in scientific journals and present the results at scientific meetings. All results in journals and presentations will be anonymous. An annual report will be published on the study website for volunteers.

## Who is organising and funding this study?

This research is being organised by the University of Southampton and funded by The Periscope project, which has received funding from the European Union Innovative Medicines Initiative. It is being sponsored by University of Southampton. There are no conflicts of interest for any of the research team working on this study.

## Who has reviewed this study?

All research in the NHS is reviewed by an independent Research Ethics Committee to protect your interests. The study has been reviewed and approved by the Health Research Authority. Samples taken during the study may be used in future research only after this future research is ethically approved.

## Expenses and payments

Volunteers will be compensated for their time and for the inconvenience caused by procedures at a rate of £15 per visit plus additional £6 travel expenses per visit. Admission will be compensated for at a rate of £200 per day. The maximum individual volunteers will be compensated is £3526 and the minimum £15. Volunteers who withdraw from the study prior to its completion will be offered financial reimbursement corresponding to the number of visits or days attended.

## What if there is a problem?

The study team are available 24 hours a day, during admission. After discharge you can contact the study team on 02381 20 4989 (working hours only) or 077 71674842 (24 hours). If you were to fall ill and require medical help after your discharge from the research facility we would advise you to contact your GP in the first instance and inform us once convenient. We will provide you with a letter explaining the study, which will contain the contact number for the research team. The doctor who reviews

you would be encouraged to contact the study team if there were any concerns about your health during the study.

The investigators recognise the important contribution that participants make to medical research, and will make every effort to ensure your safety and well-being. The University of Southampton, as sponsor of this study, has insurance in place to cover any negligent harm caused within the research activity as stated in the protocol. While the University will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. At any time during the study you will be entirely free to change your mind about taking part, and to withdraw from the study. This will not affect your subsequent medical care in any way.

### What if I wish to complain about the way the study was conducted?

If you have cause to complain about any aspect of the way in which you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you and your normal medical care will not be compromised in any way because you have taken part in a research study. Contact details for the study team and the independent Patient Support Service located within the hospital are at the end of this information sheet.

### What will happen if I don't want to carry on with the study?

If you wish to withdraw from the study you are free to do so at any time, but you may be asked take medicine to treat possible carriage with *B. pertussis* and have a telephone contact follow up for safety reasons. In such an event we would continue to use any data we collected up to the point of your withdrawal. Your compensation would be paid as a proportion of the total compensation according to the length of your participation.

### What if relevant new information becomes available?

Sometimes during the course of a research project, new information becomes available. If this happens, we will tell you about it and discuss whether you want to or should continue in the study. If you decide to continue in the study you will be asked to sign an updated consent form. On receiving new information, we might consider it to be in your best interests to withdraw you from the study.

### Prevention of 'Over Participating'

Participants participating in this study must not be concurrently receiving medications or vaccines in another study. In order to check this, you will be asked to provide your National Insurance or Passport number (if you do not have a NI number). This will be entered on to a national database, which helps prevent participants from taking part in too many clinical trials. More information can be found at [www.tops.org.uk](http://www.tops.org.uk). Your national insurance or passport number is also required to allow processing of compensation payments.

## Contact for further information

If you are interesting in taking part in this study please contact the study team:

Email: [uhs.recruitmentCRF@nhs.net](mailto:uhs.recruitmentCRF@nhs.net)  
Tel: 023 8120 3853  
Fax: 023 8120 5023

If you have any questions regarding this research study please contact the clinical research fellow Dr. Hans de Graaf or the Chief Investigator Professor R. Read.

Email: [h.de-graaf@soton.ac.uk](mailto:h.de-graaf@soton.ac.uk)  
Tel: 023 8120 4989  
Fax: 023 8120 5023

If you are a volunteer participating in the study and you would like to contact us in case of an emergency we can be contacted 24 hours a day, 7 days a week on: 077 71674842

In the event that you wish to discuss this project with an independent third party, please contact the hospital's Patient Support Service (available 9am to 4.30pm Monday to Friday)

Patient Support Service  
C Level Centre Block  
Mailpoint 81  
Southampton General Hospital  
Tremona Road  
Southampton  
SO16 6YD  
Tel no. 023 81 20 6325  
Email: PatientSupportService@uhs.nhs.uk