

Participant Information Leaflet

Research: Hand to nose transmission of *Streptococcus pneumoniae* in healthy participants: randomised control trial assessing the effect of hand washing on transmission

Would you like to take part in our research? This information leaflet tells you how you could take part. A member of our team will also discuss it with you: please ask us if you have questions. You may want to talk to other people about the study: please do so. Take your time to decide if you want to be involved.

What is the purpose of the study?

We are trying to understand more about bacteria called **Pneumococcus** and how we can reduce the spread of this bacteria.

Small numbers of these bacteria are often found in the nose which is called 'colonisation'. Usually, the carrier does not know the bacteria are there. In most adults, this is present at least once per year and more often in children.

Mild infections with pneumococcus are very common, such as ear infections in children. But pneumococcus can also infect the lung (causing pneumonia) or the brain (causing meningitis) or the blood (causing sepsis). These severe infections are very uncommon in healthy adults: about 50 cases in Liverpool per year. Very young children

and adults who are elderly or those who have other illnesses are more likely to become ill.

We have recently carried out a study which showed that these bacteria can be carried on the hands and then move into the nose by rubbing the nose or picking your nose. This movement then resulted in 'colonisation' of the bacteria in the nose in around 20% of the study participants. This reinforces the need for good hand washing especially by those that are more at risk of becoming unwell from these bacteria such as the elderly.

This is the first time a study has shown that these bacteria are spread from the hands into the nose. We wanted to use this opportunity to test an anti-bacterial hand soap to ensure it can reduce this movement. In this study, we will test a soap called Lifebuoy made by Unilever to test if hand washing with this will reduce the likelihood of transmission of pneumococcus from hands into the nose causing 'colonisation'.

We have already studied the effect of putting small numbers of the bacteria into the nose of healthy volunteers: more than 800 volunteers have been safely studied.

Do I have to take part?

No. Taking part in this study is voluntary.

Why have I been asked to take part?

We are looking for volunteers who are fit and healthy. We check for reasons which may put you at higher risk from the study. If we find any reason you may be at higher risk of infection, then we will not invite you to take part.

We also make sure that your participation will provide helpful information to us – approximately 10-15% of normal adults will carry the pneumococcus bacteria normally in their noses. Unfortunately, if you carry these bacteria in your nose at your first (screening) visit we will need to exclude you from the main part of the study. You may be invited back for one follow up visit after your screening visit to have some nasal cells taken.

You will not be eligible if:

- You are younger than 18 or older than 50
- You are a regular smoker, recent ex-smoker or have a significant history of daily smoking
- You are vaccinated against pneumococcus
- You are in close contact with those who have lower immune levels (such as young children and the elderly)

- You have taken part in similar research before (depending on which study and when)
- You are allergic to penicillins/amoxicillin and clarithromycin/macrolides
- You are pregnant or trying to conceive
- The study doctor thinks that a health condition, or medication means that you are at increased risk of infection, for example; skin disorders of hands or face, asthma, diabetes.

What happens if I choose to take part?

1. Health checks –

For safety, we check that you are healthy. This includes a clinical assessment and check the list above.

2. Consent –

We ask you to sign a consent form when you are sure you want to take part.

3. Informing your GP-

We send a letter to your GP to inform them that you are participating in the study in case you need health advice during the study from them.

4. Taking samples –

We take samples from the nose and blood (*see below*).

What kind of samples do you take?

5. **Drops of pneumococcus bacteria will be put on your hand. You will be asked to rub your nose with the area of hand exposed to the bacteria and sniff up the bacteria into your nose -**

We put a few drops with a small number of bacteria on your hands and show you manoeuvres to copy which will facilitate transmission of the bacteria from your hand into your nose. Half of volunteers will do this straight after the bacteria has been put on their hand and half will do this after washing their hands with soap.

6. **Post exposure hand washing -**

Following exposure, we will show you a how to wash your hands to ensure all the bacteria has been washed off. We will use a liquid product and UV light to ensure your hands are completely clean before the end of this visit.

7. **Monitoring–**

We will ask you to contact us daily to make sure you are well for 3-4 days (or longer if the research team thinks it is needed) then you may contact us at any time during the follow up period, if you are unwell for any reason.

8. **Monitoring visits –**

We take samples from your nose to see whether the bacteria are present over three visits.

Samples from the nose: A “nasal wash” will be taken; we gently squirt a little salty water into your nose. After a few seconds, the water runs out into a sample bowl. This will tell us about the bacteria in your nose.

Blood samples: We take blood samples from a vein in your arm (using a needle). We will only take a small amount to check that you are safe to take part in the study- this will be 5mls of blood (one teaspoon)

Nasal cells: (only for people that naturally carry the bacteria in their noses at screening day). We run a small plastic spoon along the inside of each nostril to collect small cells.

What will happen to my samples?

We will process your samples in laboratories at the Liverpool School of Tropical Medicine (LSTM) and at the Royal Liverpool University Hospital. We will measure the levels of bacteria in your nose and for the numbers of blood cells in your blood.

We ask that you “gift” your nasal samples to LSTM. We will store them so that in the future, we can go back to them with new tests to answer new questions.

What will happen at each visit?

*Visit 1:
Screening health
check and taking
samples*

We make sure you are fit to take part in the study. We ask routine questions about your medical health check your blood pressure, temperature and listen to your heart and lungs. We do the nasal wash and a blood test. For women, we check that you are not pregnant using a urine test.

 *between 1 to 7 days later*

*Visit 2:
Pneumococcus
exposure or follow
up visit*

For people who are naturally carrying pneumococcus in their noses:
We will invite you back for one final follow up visit where we will take nasal cells; unfortunately, these people will not be able to continue with the full study.

For people who are NOT naturally carrying pneumococcus in their noses:
Exposure: We use a dropper to put a small amount of water containing a small number of bacteria onto one of your hands. We will then ask you to rub your nose and sniff up to try and transmit the bacteria from your hands into your nose. Half of the volunteers will be asked to do this straight after the bacteria is put on your hand, the other half will wash their hands with anti-bacteria soap before attempting to transmit the bacteria.

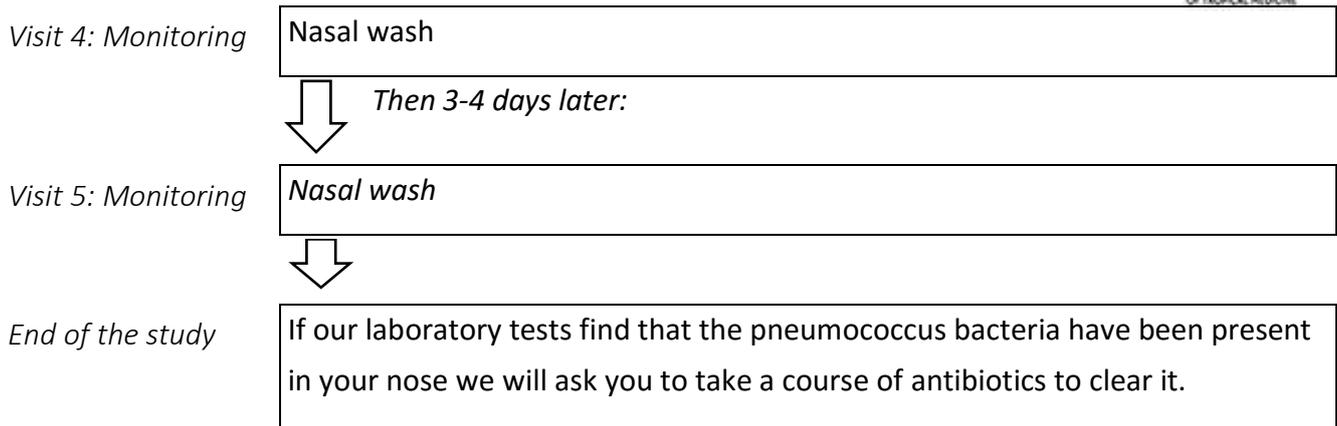
Safety: Usually, volunteers have no symptoms afterwards. There will be a doctor or nurse available by telephone 24 hours a day to answer questions. We will give you a course of antibiotics to keep with you, in case you are unwell. Each day for the rest of the working week we will ask you to contact the research team by phone or text to ensure that all is well and to check your temperature reading (a thermometer is provided).

 2 days later

Visit 3: Monitoring

Nasal wash

 *Then 4-5 days later:*



What are the risks of being in the study?

Risks of being given live bacteria

Because the bacteria are alive, there is a very small risk of infection to you or your close contacts. We do not expect anyone to develop an infection but this is why we choose participants carefully, and why we monitor them closely. We provide a thermometer and antibiotics that treat these bacteria. We give you a separate leaflet which explains the safety precautions, and what to do if you feel unwell. If you carry the pneumococcus bacteria in your nose at any point of the study, we will ask you to take the antibiotics to kill the bacteria.

As a precaution, we advise participants not to become pregnant during the study and to advise the research team if they do become pregnant.

Risks of nasal sampling

The only side effect is a little discomfort and some experience a runny nose. Taking the nasal cells may cause a little bleeding from the nose.

Risk of taking blood

There are very small risks associated with blood sampling. Some people can feel light-headed. Sometimes, may have a bruise.

What if there is a problem?

You can contact the research team 24 hours-a-day by phone. They will answer any questions, and an emergency service will be available day and night. Any medical care you need will be provided by the NHS.

What if I wish to complain?

If you wish to complain about any aspect of the study, you can contact the study doctor or nurse. The NHS complaints procedures are also available to you. Complaining will not affect the medical care you receive now or in the future.

What if I change my mind, or want to stop?

Even if you do start in the study, you are free to stop at any time and without giving a reason. If you decide not to take part, or to withdraw from the study, this will have no effect on your future health care.

If you decide to stop, we will continue to use the samples and information that we have already collected unless you tell us not to. You will be paid for the visits completed up to that point.

If you decide to leave the study after you have been exposed to the bacteria, we may need to contact you with the results of any samples we have taken and may advise you to take the three-day course of antibiotics provided to ensure we have eliminated any bacteria that we have exposed you to.

Will my details be kept confidential?

Yes. For safety, we collect information about your medical history and contact details before you take part. The clinical research team use this information to check you are healthy, and to contact you when needed.

We will also collect information which allows us to understand more about the samples, for example, your age or sex. However, those outside of the clinical team are never given information that can identify you. Your samples

are given a unique number, and your name is not used.

We will ask your permission to inform your GP that you are taking part in the trial as this may be relevant to your medical care outside the study. We do not expect to find anything which would affect your health care. If we do, we will let you and your GP know about it.

All data will be collected and stored at the Accelerator Research Clinic at the Liverpool School of Tropical Medicine. It will be stored for a minimum period of 10 years. Your medical notes and research data are may be looked at by those who monitor the research.

What are the benefits of taking part?

There are no direct benefits to you. You will be a part of what we believe is a valuable research study that may help us to improve medical care for others.

How much will I get paid?

The money you are paid is compensation for inconvenience, loss of income, and possible risks of taking part. Our payments are below.

Experimental Human Pneumococcal Carriage Model



Payment – for people not carrying pneumococcus at screen		
Visit 1: Screening and samples	30 min	£30
Visit 2: Exposure to pneumococcus and hand washing. This includes you making daily SMS/telephone contact for 3-4 days. (We will withhold £5 per day if you do not contact us)	30 min	£60
Visit 3: Nasal samples	20 min	£10
Visit 4: Nasal samples	20 min	£10
Visit 5: Nasal samples	30 min	£10
	Total	£120

Payment – people naturally carrying pneumococcus at screen (10-15% of participants estimated)		
Visit 1: Screening and samples	30 min	£30
A proportion of natural carriers may be asked to come for visit 2: follow up visit where nasal cells are taken	10 min	£10
	Total	£30 or £40

Contact details

General questions: please contact the research team on 0151 702 9486 during normal working hours.

Web site: <http://www.lstmed.ac.uk/research/topics/pneumonia>

Emergency contact details at any time day or night:

Mobile: 07740 410 290

Phone: 0151 702 9486

Please ask for the study team for the “Respiratory research team or EHPC team”

The Chief Investigator for this study is Dr Andrea Collins. You may contact her at the Liverpool School of Tropical Medicine, Pembroke Place, Liverpool, L3 5QA, UK. Andrea.collins@lstmed.ac.uk

This research is sponsored by the Liverpool School of Tropical Medicine. It is funded by the Unilever. The National Research Ethics Service Committee Liverpool East has reviewed the study and given approval for it to take place.