Participant Information Leaflet

Research: Lifebuoy Bar Soap Handwashing Randomised Control Trial

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 a bacteria called **Pneumococcus** and how we can reduce its spread.

Small numbers pneumococcus are commonly found in our noses; this is called 'colonisation or carriage'. Usually, the 'carrier' does not know the bacteria are there. Most adults are 'carriers', at least once per year.

Mild infections with pneumococcus are very common, such as childhood ear infections. Severe pneumococcal infections are uncommon in healthy adults but can affect the lungs (causing pneumonia) or the brain (causing meningitis) or the blood (causing sepsis). Very young children, older adults or those who have other illnesses are more likely to get pneumococcal infections.

We have recently carried out a study which showed for the first time that these bacteria can be carried on the hands and then move into the nose by rubbing or picking your nose, where they can stay - resulting in 'carriage' in around 20% of participants. This reinforces the need for good hand washing especially with regards to those that are more at risk of becoming unwell from these bacteria such as the elderly.

In this study we are testing if Lifebuoy bar soap can reduce this movement or transmission, when compared with water alone or no hand washing.

We have studied the effect of putting small numbers of the bacteria into the nose for nearly 10 years, with more than 1200 participants being studied safely.

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.

Approximately 10-15% of normal adults will carry the pneumococcus bacteria normally in their noses. If you are carrying these bacteria in your nose at your first (screening) visit, we may invite you back for a repeat nasal wash around 4 weeks later to see if you are still a carrier. This may be repeated twice. If you are no longer carrying the bacteria, you may be included in the study and you will attend a second reduced screen visit (limited

clinical exam, pregnancy test and blood sample as required).

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 immunosuppressed people)
- 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. **Consent**
   We ask you to sign a consent form when you are sure you want to take part.
2. **Health checks**
   For safety, we check that you are healthy. This includes a clinical assessment and check the list above.
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*).
5. **Pre-exposure**
   We will clean your hands by spraying ethanol onto your hands and ask you to rub this all over your hands to remove as much bacteria as possible from your hands **prior** to the exposure. Randomisation will occur on the day of the exposure, the clinical team are not able to predict or affect the group that you are allocated to, this is done by opening an envelope that has been computer generated.
6. **Exposure**
   A few 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 ('transmission manoeuvre')
   You will be randomly allocated to one of three groups:
   Control group: no handwashing prior to the transmission manoeuvre
   Intervention A: Hand washing with water only prior to the transmission manoeuvre
   Intervention B: Hand washing with Lifebuoy antibacterial soap prior to the transmission manoeuvre.
7. **Post exposure hand washing**
   You will be seated comfortably in a reclined chair for 15 minutes after the transmission manoeuvre. Following exposure, we will show you 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.
8. **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.

9. **Monitoring visits**

We take samples from your nose to see whether the bacteria are present over three visits at day 2, day 6/7 and day 9/10 post exposure.

10. Study completion

At the end of the study (Day 9/10) you will be asked to take the antibiotics for 3 days if your nasal wash samples have detected the pneumococcal bacteria at any timepoint following the exposure visit. If your samples have tested negative for pneumococcus throughout, you will be asked to return your antibiotics to a pharmacy for destruction.

What kind of samples do you take?

Samples from the nose: A "nasal wash" will be taken; we gently squirt a little salty water into your nose. After a few seconds, you will be asked to expel the liquid by blowing out through your nose, the liquid is collected 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).

What will happen to my samples?

The samples taken during this study will be processed and stored in the LSTM and at the Royal Liverpool University Hospital. These samples will be gifted for future use in ethically approved research.

At the end of the study, remaining samples will be transferred to a research tissue bank held at LSTM. All samples will be anonymised at the point of sampling. The stored samples will be analysed as and when new technology becomes available, when new scientific questions arise relating to protection and susceptibility of respiratory disease. Samples may be sent to national and international collaborating laboratories for their expertise however all identifiable information will be removed.

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, listen to your heart and lungs, measure your height and weight. We take a 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* Day 0	**Exposure:** We will open the randomisation envelope and inform you of your allocated group. We will demonstrate the transmission manoeuvre to you and ask you to practice it. We will clean your hands using ethanol spray and ask you to run it all over your hands to remove as much bacteria as possible prior to the 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 immediately (Control) following hand washing with water (Intervention A) or following hand washing with Lifebuoy soap (Intervention B). You will be seated for 15 minutes in a reclining chair. **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).
Visit 3: Monitoring Day 2	Nasal wash
Visit 4: Monitoring Day 6/7	Nasal wash
Visit 5: Monitoring Day 9/10	Nasal wash
End of the study	If our laboratory tests find that the pneumococcus bacteria have been present in your nose, we will ask you to take a course of antibiotics to clear it.

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, therefore we choose participants carefully, and 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 at the end of the study.

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 wash

The only side effect is swallowing some liquid and some experience a runny nose.

Risk of taking blood

There are very small risks associated with blood sampling. Some people can feel light-headed however it is a very small volume. 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 or the study sponsor by email: lstmgov@lstmed.ac.uk. 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. 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 time and inconvenience and loss of income. Our payments are below.

Payments will be made by bank transfer within 3 weeks of completing the study.

Payment		
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	£40
Visit 3: Nasal samples	20 min	£10
Visit 4: Nasal samples	20 min	£10
Visit 5: Nasal samples	30 min	£10
Repeat nasal wash (If natural carrier at screen) May be repeated twice after 4 weeks	5 min	£10
Re-screen (Limited clinical exam, samples as required)	15 min	£20
	Total	**£100-£140**

Contact Details

General questions: 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. Please ask for 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.

*The Chief Investigator for this study is **Dr Andrea Collins**. You may contact her at the Liverpool School of Tropical Medicine, Liverpool Life Sciences Accelerator Building, 1 Daulby Street, Liverpool, L7 8XZ, UK. Telephone: 0151 702 9439. This research is sponsored by the Liverpool School of Tropical Medicine and the Royal Liverpool and Broadgreen University Hospitals. It is funded by Unilever. The research has been reviewed for scientific content by an external panel. The National Research Ethics Service Committee Liverpool East has reviewed the study and given approval for it to take place.*

Liverpool School of Tropical Medicine (LSTM) is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records 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. LSTM will keep identifiable information about you 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting dataprotection@lstmed.ac.uk.

LSTM will use your name, NHS number and contact details 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. Individuals from LSTM and regulatory organisations may look at your medical and research records to check the accuracy of the research study. LSTM (research site) will pass these details to LSTM (sponsor) along with the information collected from you and your medical records. The only people in LSTM who will have access to information that identifies you will be people who need to contact you to regarding your participation in the research or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

LSTM (research site) will keep identifiable information about you from this study for 10 years after the study has finished.

LSTM will collect information about you for this research study from you and/or your GP records. Your GP will not provide any identifying information about you to LSTM. We will use this information to confirm your eligibility. This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

Consent Form

Participant Study number

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If you agree with each sentence, please **INITIAL** in the box. Then, print and sign your name below and add today's date

I have read and understand the information sheet version **2** for the above study. I have been able to consider the information and to ask questions.	Initial
I gift my nasal samples to LSTM. I consent to their long-term storage, and to their future use in medical research in the UK and overseas.	Initial
I understand that this study is voluntary and that I am free to withdraw without giving any reason without my medical care or legal rights being affected.	Initial
I understand that relevant sections of my medical notes may be reviewed by the clinical research team if deemed necessary.	Initial
I agree to my GP being informed of my participation in the study.	Initial
I agree to provide details of a contact who, in the event of an emergency, could be contacted on my behalf.	Initial
I confirm that I am not planning to conceive, and I will use effective contraception if required during the study.	Initial
I understand that my samples will be transferred to a research tissue bank at the end of the study for future use in ethically approved research.	Initial
I agree to take part in this study.	Initial

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Name of participant Signature Date

…… …… _ _/_ _ _/_ _ _ _
Name of person taking consent Signature Date

Original copy to site file; 1 copy to participant; 1 copy; 1 copy in CRF