Preventing Pneumo 2

Preventing pneumococcal disease through vaccination

Participant Information Leaflet (PIL)

Would you like to take part in our research? This information leaflet tells you how you could. A member of our team will also fully 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.

Who are we? What kind of research do we do?

We are the Respiratory Infection Team at the Liverpool School of Tropical Medicine (LSTM)- The study sponsor. We conduct world-leading research into bacteria (a type of germ) called pneumococcus, of which there are over 90 strains. Pneumococcus can cause mild (e.g. ear) infections or more serious infections such as pneumonia (lung infection), meningitis (brain infection) or sepsis (blood infection).

Pneumococcus is often found in the nose of healthy adults (at least once per year) and more often in children – these people are called "carriers". Usually, the bacteria come and go without causing disease, but in some people, it can cause illness.

Our research has shown that small numbers of this bacteria living in the nose ("nasal carriage") may be protective against future carriage and therefore, potentially against disease. We call this an Experimental Human Pneumococcal Challenge (EHPC) model. This will allow us to learn about the immune response in the body to 'carriage' and better learn how people are protected from infection in the nose. The EHPC model also allows us to research how to develop improved and new pneumonia vaccines. More than 1,500 participants have already been studied safely using this method of putting pneumococci in the nose using 4 different pneumococcal strains: 23F, 15B, 3 and 6B.

What is the purpose of the study?

In the UK, there are 2 vaccines currently used to provide protection against pneumococcus. PCV-13 (Prevenar 13®) protects against 13 (of >90) strains of pneumococcus and is routinely given to children <2 years of age. PPV-23 (Pneumovax 23®) protects against 23 strains and is routinely given to adults >65 years of age. Some countries such as the US also recommend PCV13 for older adults >65 years of age. Both are also used in children and adults with medical conditions that put them at higher risk of pneumococcal disease. PCV-13 has been shown to prevent carriage from many pneumococcal strains, particularly in children but PPV-23 has not. However, in adults the duration of protection and whether PCV-13 can protect against a very important strain – type 3 – are not known.

Research studies have shown that there is an increase in carriage and disease by some strains that should be covered by these vaccines. We do not know why this is occurring and want to learn more about how these vaccines affect pneumococcal carriage.

In this study we are exploring how these 2 vaccines, when compared to a placebo (saline), affect nasal carriage in adults with 2 different strains of pneumococcus – strains 3 and 6B. In this study we are aiming to recruit a total of 516 healthy adults aged 18-50 years old.

Do I have to take part?

No. Taking part in this study is voluntary. If you decide to participate, you can withdraw from the study at any time.

Who can take part in the study?

We are looking for participants that are fit and healthy and aged 18-50 years old. We will check for reasons that may put you at higher risk for taking part in the study. We also make sure that your participation will provide helpful information to us. If we find any reason that you may be at higher risk of infection, then we will not invite you to take part.

You are potentially eligible if you:

- Are male or female aged 18-50 years (inclusive)
- Speak English fluently – to ensure a comprehensive understanding of the research project and your proposed involvement
- Have the capacity to give informed consent
- Have a urine pregnancy test and agree to use adequate contraception during the study *(only if you are a female of childbearing age)*

You are not eligible if any of the following apply to you:

Research participation:

- You are currently involved in another research study (unless observational or non-interventional; exceptions are the EHPC bronchoscopy study and Covid-19 observational and interventional trials)
- You took part in a previous EHPC study in the last 3 years where you were exposed to pneumococcus

Vaccination:

- You have previously received a pneumococcal vaccination.

Allergy:

- To penicillin or amoxicillin
- Have had a severe, life-threatening allergic reaction to a vaccine

Health history:

- Chronic ill health (e.g. problems with your immune system, diabetes, asthma [taking regular medication], recurring ear infections, COPD, major heart/lung disease, cancer, rheumatoid arthritis)
- Taking medication that may affect your immune system (e.g. steroids, nasal steroids, Roaccutane, anti-rheumatoid drugs)
- Recently received antibiotics (within the last 28 days or long-term for a chronic infection)
- Pneumococcal illness requiring stay in hospital within the last 10 years
- Any uncontrolled medical/surgical conditions (such as but not restricted to mental health conditions, epilepsy, narcolepsy or chronic pain) at the discretion of the study doctor
- Any other condition that may put your safety or the study at risk (decided by the clinical team)

Taking medication:

- That may affect the immune system e.g. steroids, inflammation altering (e.g. nasal steroids, Roaccutane) or disease-modifying anti-rheumatoid drugs.
- Long-term use of antibiotics
- Nitroglycerin
- That affects blood clotting (any oral/injectable anticoagulants [except aspirin]).

Direct caring role or close contact: with individuals at higher risk of infection or belonging to the extremely vulnerable group as defined by Public Health England (PHE) (children under 5, people with chronic ill health/immunosuppression) on a regular basis during the study

Smoker:

- You are a current or ex-smoker (in the last 6 months) – regular cigarettes/cigars/e-cigarette/vaping/recreational drugs
- Previous significant smoking history – more than 20 cigarettes per day for 20 years or the equivalent (>20 pack years)

Pregnancy: If you are pregnant, lactating or intend on becoming pregnant during the study.

History of or current drug or alcohol abuse: as assessed by the clinical team

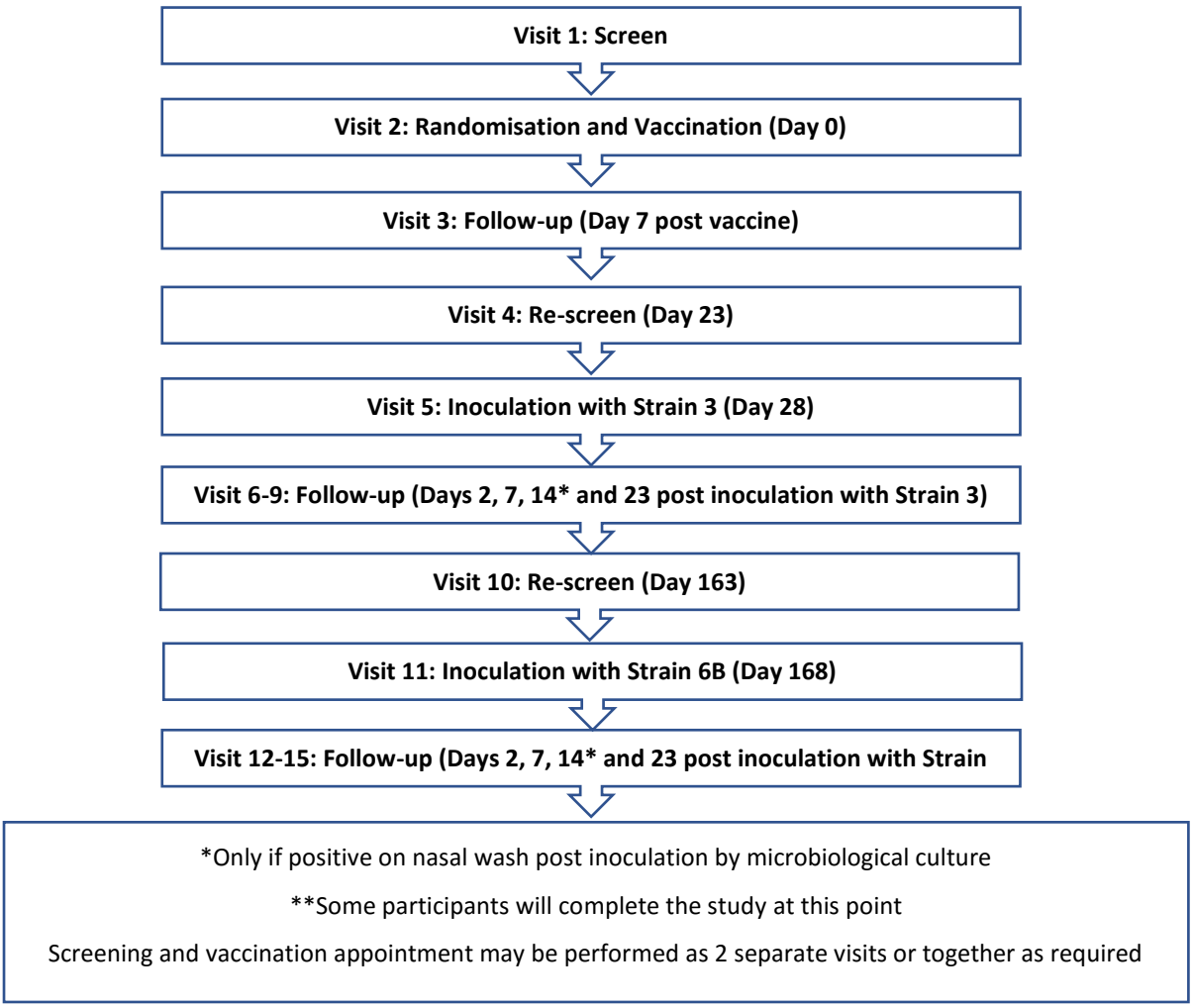
Significant mental health problems (uncontrolled condition or previous admission in a psychiatric unit at the discretion of the clinician) that would impair your ability to participate in the study

Overseas travel: planned during the 'exposure' stages of the study (from the time of inoculation until you take antibiotics)

What happens if I choose to take part?

If you choose to take part in this study and the research team agrees that you are suitable, you will be asked to sign a consent form. A copy of this information leaflet and your signed consent form will be given to you to keep. You may have a clinical blood sample taken on the day of consent to check that you are eligible to take part.

You would need to then attend approximately 15 clinic visits over about 8 months and we will take a blood sample at 13 of those visits. Clinic visits occur at the Accelerator Research Clinic in the Liverpool Life Sciences Accelerator Building and/or The Well-Travelled Clinic



What will happen at each visit?

Screening Period	
Initial Visit	A member of the research team will discuss the study with you in a group presentation in a Covid-19 secure environment. You will have the opportunity to ask questions and discuss the study directly with a researcher in private following the presentation. If you are happy to take part in the study, you will be asked to complete a questionnaire to demonstrate that you understand the study involvement before signing a consent form. We will ask you questions to assess whether you are eligible to take part in the study. This will take about an hour. We may opt to carry out this visit via phone or video-call instead. In that scenario, we will ask you to sign the consent form in person, during your screening visit. If we need further information about your medical history to confirm your eligibility, we may request your GP complete a GP questionnaire or provide your medical summary. We may take a clinical blood sample during this visit to confirm that you are eligible to proceed. We will also ask you to provide us with your National Insurance number (or passport number if you do not have a National Insurance number). This is entered onto a national database which prevents volunteers from taking part in too many clinical trials. The Trial Over-volunteering Prevention Service (TOPS) database is to ensure safety of all our participants. More information can be found at https://www.hra.nhs.uk/about-us/committees-and-services/the-over-volunteering-prevention-system/.
Screening and Vaccination Visit (Injection into your arm)	We will ask some routine questions about your medical health, your vaccination history and medications you are taking. We will take your blood pressure, heart rate and temperature, and we will carry out a brief examination. This is all done to make sure you are fit and well. Females of childbearing potential will have a urine pregnancy test. We will take blood, throat swabs, nasal wash, urine sample and a Covid swab/ saliva sample (plus nasal cell sample on a subset of participants).* If the screen and vaccine visits occur separately, all samples described above will be taken on the screen visit. You will have one small blood sample taken on the day of the vaccine, a urine pregnancy test may be repeated if required. You will be randomly assigned to receive 1 of 3 different injections: 1 of 2 vaccines (PCV-13 or PPV-23) designed to protect against the pneumococcus bacteria, or a saline injection. You are assigned which injection you are to receive and what bacterial strain you receive at 1 month challenge by a computer system. You will be allocated to 1 of 5 groups as below: • PCV-13 with strain 1a; • PCV-13 with strain 2; • PPV-23 with strain 1a; • Saline injection with strain 1a; • Saline injection with strain 2.

	Up to 104 participants will be allocated to each of the 5 groups. Neither you nor the research team can influence what injection or strain you receive. You will not be told which vaccine or placebo you are to receive, and you may be asked to wear a physical blindfold (single use) when the research nurse gives you your injection. The time will be kept to a minimum and will help to ensure the vaccine is unidentifiable to you. You will have a single injection into the muscle in your upper arm. Please ensure you wear clothing which allows access to your arms (e.g. short sleeved shirt). You will be asked to remain with us for 15 minutes after your vaccination to ensure you do not have an immediate allergic reaction. This visit will take up to 90 minutes. * The types of samples are outlined in the next section. If the screen and vaccination visit occurs separately, most samples will be taken on the screen visit; nasal cells on some participants and one blood sample will be taken on the vaccination visit.
Vaccination	
Follow-up Visit (Day 7)	You will come back into the Accelerator Research Clinic (ARC) 7 days after your vaccination where you will have a blood and urine sample taken.
Inoculation	
Re-screening (1- and 6-months post-injection)	Approximately 1 and 6 months after your vaccination, you will have a few samples taken, including blood, nasal wash, throat swab, urine samples and a Covid swab/saliva sample (a subset of participants will also have nasal cell samples taken). You will also have a clinical blood sample taken prior to your second inoculation to ensure you remain fit and well and a brief clinical examination.
Inoculation Visit (Putting the bacteria into your nose)	We use a dropper (pipette) to put a small amount of water containing a small number of pneumococcus into each nostril. You will be 'inoculated' with a dose of the bacteria (80,000CFU*) in each nostril. You will lie down in the clinic for 15 minutes after the procedure and will have a blood sample taken. A brief clinical examination may be carried out. You may be asked to complete a daily symptoms questionnaire, this will be completed prior to inoculation and daily for 7 days following each inoculation. At the end of your visit, you will be given a safety pack as described below. Usually participants have no symptoms afterwards. There will be a doctor or nurse available by telephone 24 hours a day, 7 days a week to answer questions. We will give you a safety pack to keep with you, this includes: • A course of antibiotics to keep with you in case you are unwell • A thermometer to check your temperature at home • A safety information sheet • A study contact card You will then be ready to return home. We will ask that you inform us of your temperature and symptoms daily for the next 5 days using text message or an App available on iPhones/Android phones or

	through the symptoms questionnaire. If you are feeling unwell, you should contact the research team at the provided number. Please phone us if it is urgent. * CFU = colony forming units or, the number of individual bacteria
Monitoring Period	
Clinic Visits on day 2, 7, 14* and 23 post-inoculation	At each visit, a few samples will be taken which may include blood, throat swabs, nasal wash and urine samples (plus nasal cell sample on a subset of participants). We may also perform a brief clinical examination.
Covid-19 screening	Prior to each visit you will receive a text or email to remind you of your appointment to ensure you do not have any Covid-19 symptoms. If you do, you will be temporarily excluded from the trial and advised to seek a test through the community testing. During your screening visits, we will also be carrying out Covid-19 testing. If any of these come back positive, you will be asked to isolate and be temporarily excluded as per PHE advice or longer. These measures will ensure we are operating in a Covid-19 secure environment to protect participants and staff.
End of the study	All participants will be asked to take the antibiotics* from the safety pack to clear/reduce the amount of pneumococcus in their nose after the first inoculation with strain 3 (1-month inoculation). Participants that become carriers after the second inoculation with strain 6B (6-months) will be asked to take the antibiotics from the safety pack to clear/reduce the amount of the pneumococcus. *Amoxicillin 500mg three times per day for 5 days (1-month inoculation) or for 3 days (6-month inoculation)
* Day 14 visit will occur only if positive on nasal wash microbiology test post inoculation. Subgroup of participants only will complete the 2nd inoculation at 6 months including the follow-up visits. Subgroup of participants will complete the study after day 23 post inoculation of strain 3.	

What samples do we collect from you?

We collect nose, throat, saliva, urine and blood samples to look at the immune response and for the bacteria:

Nasal wash: 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 and your immunity.

Throat swab: We take a small cotton swab and wipe the back of your throat in a circular motion. This is used to detect bacteria and viruses in your throat.

Covid swab/Saliva: We use a small cotton swab and wipe the back of your throat and nose. This is used to detect the Covid-19 and other viruses. Saliva may be used as an alternative to detect Covid-19.

Nasal cells: A subgroup of participants will be invited to donate nasal cell samples. We insert a very small and narrow plastic spoon (about the size of a toothpick) into the inner surface of the nose that is withdrawn in a sweeping motion to collect small cells. We will perform this twice on each nostril. We will look at what kinds of cells in your nose affect whether you are susceptible or protected against nasal carriage of the bacteria.

Blood samples: We take blood samples from a vein in your arm (using a needle). We will take up to 80mL (about the same as 8 tablespoons) during a visit. This amount of blood is safe to give, and your body will replace this blood quickly. We will look at your immune response to the vaccines or placebo and to the bacteria. We will also assess if there are genetic factors which affect protection or susceptibility to the bacteria.

Urine: We take a small amount of urine (20mL) to test for the bacteria. A urine pregnancy test will be performed at screening and re-screen visits or as required if there has been significant time since the last visit on women of childbearing potential.

What side effects or risks can I expect from this study?

The risks that you should consider *before* participation in this study are the risks associated with vaccination, venepuncture, nasal sampling and inoculation with live bacteria.

Vaccination: As both PCV-13 and PPV-23 are licensed vaccines we do not anticipate any causes for concern. The research nurses and doctors will monitor any symptoms you experience at each visit and will be available 24-hours a day by phone if needed.

Like all vaccines, the PCV-13 and PPV-23 vaccines can cause side effects in some people. If you do experience side effects, they usually happen in the first few days after vaccination, they are generally mild, and they do not last a long time. The most common side effects (seen in more than 1 out of 10 people who are vaccinated) of these vaccines are:

- Pain, swelling, tenderness or redness at the site of injection
- General side effects including headache, nausea (feeling sick), vomiting, decreased appetite, generally feeling unwell, diarrhoea, muscle or joint pain, rash, fever or chills.

Please read the Patient Information Leaflet for PCV-13 and PPV-23 vaccine provided for complete information on these vaccines.

As with any medication or vaccine, unexpected, severe allergic reactions may very rarely occur (approximately 1 in a million chance). This type of allergic reaction, called anaphylaxis, can be recognised by itchy skin rash, swelling of the face, difficulties breathing and swallowing, or by a sudden drop in blood pressure. If such a reaction occurs, it usually starts very soon after vaccination. This is why it is important you stay in the clinic for at least 15 minutes after vaccination where the research nurses and doctors can monitor you and have medical equipment and training to manage an allergic reaction.

In rare cases, side effects can be serious or prolonged, but in the vast majority they are minor as detailed above It is important to let the research nurses or doctors know if you are worried about your symptoms.

You may take medicines after your vaccination to help reduce side effects. For example, you may take paracetamol to treat a fever or pain. We ask you to let the research nurses or doctors know if you've taken any medication.

We do not anticipate participants to have side effects from the saline injection. However, participants receiving the saline injection will be monitored in the same way as participants receiving PCV-13 or PPV-23.

Inoculation with pneumococcal bacteria: Because the bacteria are alive, there is a very small risk of infection to you or your close contacts. We have experience of using this model safely in more than 1,500 healthy participants with no serious side effects. In one of our previous studies, particularly at higher doses, some participants developed a sore throat which was either self-limited or resolved without any complications following a short course of antibiotics. We provide a safety pack as described above and you have access to the research team by phone 24/7. We give you a separate leaflet which explains the safety precautions and what to do if you feel unwell.

Blood sampling: The risks associated with blood sampling (venepuncture) are minimal, but this may cause temporary pain, bruising and/or bleeding to your arm. The blood sampling will be performed by trained healthcare professionals. In the rare circumstance that we notice anything unusual or medically significant about your blood then we would let you know and ask if we could inform your GP.

Nasal sampling: There are limited risks connected with these samples. During a nasal wash, you may swallow a small amount of salty water, however, this is harmless. The nasal cell sample is slightly uncomfortable and may make your eyes water – this is very brief. Sometimes a small amount of blood can be seen on the sample probe, however, it is rare for it to cause a nosebleed. The research nurses and doctors are trained to treat you in clinic if you have a nosebleed.

Throat swabs/ Covid throat/ nose swabs: There are limited risks associated with these samples. These samples may make you feel some discomfort, gag a little. A small amount of blood can be seen occasionally on the nasal sample probe, however, it is rare for it to cause a nosebleed.

Saliva and urine sampling: There are no adverse effects of the saliva or urine sampling.

Risks related to the Covid-19 pandemic: There are risks associated to the Covid-19 pandemic and disease transmission. However, we have taken measures to carry out the study in a Covid-19 secure environment. We have experience with carrying out more than 1000 appointments during the pandemic without any cases of disease transmission. See separate section below for more information.

What if there is a problem?

The research team is available to contact 24 hours-a-day by phone. Please contact us as soon as possible if you are unwell or if you develop any symptoms including but not exclusive to sore throat, earache, headache, fever, cough, breathlessness, lack of taste or smell.

We would also like to know about any new health or medication changes. Any medical care you need will be provided by the NHS.

The study is sponsored by the LSTM and has appropriate insurance coverage in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

What will happen to my samples?

The samples taken during this study will be processed and stored in the LSTM, Liverpool University Hospitals NHS Foundation Trust (LUHFT) and Pfizer Inc.

Samples are taken to look at your immune response to the vaccine and the bacteria as well as whether you are carrying the bacteria in your nose. These experiments may involve the extraction of molecules such as DNA. DNA is what makes up the genes in your cells and can be used to see if there are genetic factors that affect protection or susceptibility to these bacteria. These samples may be processed at LSTM and/or shared with, Pfizer Inc. or other external collaborators nationally and internally

Blood samples are also taken to check your eligibility and safety during the study, and these will be sent to the LUHFT.

We would also seek your consent to gift any leftover samples to be used for ethically approved research at the end of the study. These samples will be transferred to a research tissue bank held at LSTM. The stored samples will be analysed (including genetic analysis) as and when new technology becomes available, or when new scientific questions arise relating to protection and susceptibility of disease. If you consented, your leftover samples would be stored indefinitely.

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

If you do start 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 won't affect your future healthcare.

If you decide to stop, we will continue to use the samples that have already been taken and information that we have already collected from you – no further samples or data will be collected. You will be paid for the visits completed up to that point.

If you have been inoculated with the Pneumococcus bacteria and have become a nasal carrier, we will ask you to take your antibiotics and we will follow-up with you until you have finished them to ensure your safety.

The study team may stop your involvement in the study for the following safety reasons:

- If you develop a condition that is in the exclusion criteria
- If you start a new medication that is prohibited
- If you become pregnant
- If you are unable to follow study instructions or the team are unable to contact you. Please contact study team if you become pregnant, start a new medication, or develop a new medical condition.

Will my details be kept confidential?

Yes, your personal information will be kept confidential and handled in accordance with data protection laws in the UK.

The research team will 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 that allows us to understand more about the samples, for example, your age or sex. Research data and samples that are collected during the study will be pseudonymised; this means your personal details will be removed from data and samples we collect from you for the purposes of our research (or future research) so that you are not identifiable. A participant number will be used to identify your data and samples instead. Data and samples may be transferred outside of the UK e.g. to Pfizer Inc in the United States, where data protection laws may differ from the UK. Data that is transferred elsewhere will be anonymous. Publications from our research will be anonymous and cannot identify you in any way.

We will ask your permission to inform your GP that you are taking part in the study as this may be relevant to your medical care outside the study. We will also ask for your GP to confirm your health, vaccination and medical history if indicated following the screening questions. We do not expect to find anything which would affect your healthcare. If we do, we will let you and your GP know about it.

The blood samples we collect to assess your eligibility and safety will be processed in an NHS laboratory and results from these samples are connected to your NHS record. The clinical team will only access the results of your blood tests for these purposes. Your details and results from these samples are safeguarded under the trusts data protection policy and will only be accessed during the study by the researchers to assess your safety and eligibility.

Data collected during the study and your research and medical notes may be looked at by independent monitors, auditors, regulatory authorities or the funding body (Pfizer Inc.). They will be assessing the quality of the trial to ensure that it is conducted according to applicable regulations. The information you provide us in order to process trial payments in the study will be accessed by members of the financial team at LSTM. All data will be stored at the LSTM for up to 25 years. Data and samples sent to Pfizer will be stored for up to 15 years after which, they will be destroyed.

What are the benefits of taking part?

You will be a valuable part of a research study that we hope will eventually lead to the development of new methods to prevent respiratory infections through vaccination. You may learn more about your general health and wellbeing and may receive some protection against pneumococcal disease.

What if I wish to report a concern?

If you wish to report a concern about any aspect of the study, you can contact the research nurses or doctors via telephone on 07740 410 290 or 0151 702 9424. You can also contact the sponsor (The Liverpool School of Tropical Medicine) by emailing lstmgov@lstmed.ac.uk. Reporting a concern will not affect the medical care you receive now or in the future.

How much will I get paid?

The money you are paid is compensation for your inconvenience, time and possible discomfort from taking part in the study. The first payment will be made at the end of part one (1-month challenge) and the second at the end of the study. Payments will be made by direct bank transfer about 3 weeks after the final visits. If you withdraw from the study for any reason, you would be paid for the visits you attended only.
Bank details will be kept confidential. Personal information such as your name, address and bank details will be shared with the LSTM finance team to process or verify your payments. Financial auditors may also audit the records where this information is held. All confidential data will be stored according to the General Data Protection Regulation (GDPR).

Procedure	Duration	Number of Visits	Payment
Initial visit (study information, eligibility questions, informed consent, consent quiz, clinical blood sample, GP questionnaire if indicated)	60 mins	1	£0
Screening and vaccination appointment (clinical exam, vital signs, medical history, research samples, randomisation and vaccine administration)	90 mins	1	£60
Screening appointment if performed separately (clinical exam, vital signs, medical history, research samples and clinical blood sample)	30 mins	1	£30
Randomisation and vaccination appointment if performed separately (vital signs, blood sample, randomisation and vaccine administration)	60 mins	1	£30
Re-screen appointments (clinical exam, vital signs, medical history, research samples, clinical blood sample may be repeated)	20 mins	2	£20
Inoculation with pneumococcus (1-month and 6-month challenge) *Also includes you making daily telephone contact for the first 5 days; contact payment may be withheld if you do not make daily contact.*	45 mins	2	£40 *Includes the daily contact at £5/day*
Clinic visit samples on day 7 (post-vaccination), day 2, 7 and 23 (post 1-month and 6-month challenges)	15 mins	9	£15

Clinic visit samples on day 14 (post 1-month and 6-month challenges)	5mins	2	£10
Nasal cell samples taken in subset of participants (vaccination, day 7 post check, re-screen, day 2, 7, 23 [post 1 month and 6 month challenge])	5mins	10	£5
Retention payment for those taking part in Part A and B, to be paid at the end of Part B	0mins	1	£50
Total remuneration Part A ONLY £190 (attending all visits) **Part A and Part B £355 (attending all visits without nasal cells)** **Part A and B £405 (attending all visits with nasal cells)** **Payments will be made in 2 installments at the end of Part A and Part B**			
If you refer a friend and they take part in the study, you will receive a £10 payment or a shopping voucher of equivalent value			

What will happen at the end of the study?

At the end of the study, the clinical team will inform you if you received the PCV-13 vaccine, PPV-23 vaccine or saline injection. We will also inform your GP in a letter.

The results of the research will be published in a scientific medical journal – this can often take a few years. We will send you a letter containing the results (which are also published on our website).

How do I contact the study team?

General inquiries: Please contact the research team on 07740 410 290 or 0151 702 9424 during normal working hours. Alternatively for general study information, you can go to our website: https://www.lstmed.ac.uk/pneumoniavaccine or visit the International Standard Randomised Controlled Trials Number (ISRCTN) registry: <insert weblink for trial> or https://www.clinicaltrials.gov/<insert weblink for trial>

Emergency phone number (24/7): 07912 053 981

The Chief Investigator for this study is **Dr Andrea Collins**. You may contact her at the Liverpool School of Tropical Medicine (LSTM), Liverpool Life Sciences Accelerator Building, 1 Daulby Street, Liverpool, L7 8XZ, UK. Telephone: 0151 702 9439.

What happens if I am offered a Covid-19 vaccine via my GP or workplace?

As the national vaccination rollout progresses, you might be offered a Covid-19 vaccine via your GP or workplace. If this is planned and we are made aware during your screening visits, we will delay your enrolment to facilitate your planned Covid-19 vaccination allowing 3 weeks between the Covid vaccine and the start of this study. If it is not, and you are offered a Covid-19 vaccine while enrolled in the study, we may help to facilitate your Covid-19 vaccination. We would advise that you allow at least 3 weeks between the study vaccination and the Covid-19 vaccination. You will be able to remain in the study and carry on with the visits as detailed above, with the possibility of minor adjustments to the schedule.

Protective measures in place against Covid-19 infection

To protect participants and staff, we will use infection control procedures in line with the latest Public Health England (PHE) guidance throughout the study. Face coverings are mandatory in all spaces, and we are using a one-way system. Frequent hand-hygiene with alcohol gels is encouraged. If you test positive for Covid-19 at screening, you will be temporarily excluded from the study to reduce the risk of onwards transmission to other study subjects and study staff. Samples provided up to that point will be retained, and participation will be continued after the isolation period as suggested by PHE or longer.

If a participant does develop symptoms suggestive of Covid-19 infection (e.g. fever, cough, shortness of breath, lack of smell or taste) they will be advised to follow the latest PHE guidance regarding self-isolation. A clinical review by medical staff will occur in a designated 'Covid-19' zone to clarify whether their symptoms are related to Covid-19 infection or pneumococcal challenge (if post inoculation). A Covid-19 nasopharyngeal swab will be performed at this visit and all further participant study visits suspended until this clarified. If a study participant becomes acutely unwell with Covid-19 symptoms, they will be advised to seek urgent medical attention via regular routes of healthcare.

Further information

This research is sponsored by the LSTM and is funded by Pfizer Inc. The research has been reviewed for scientific content by an external panel. A National Research Ethics Service Committee has reviewed the study and given approval for it to take place.

The 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.

Your rights to access, change or move your information is 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 may 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 regarding your participation in the research or audit the data collection process.

LSTM (research site) will keep identifiable information about you from this study for up to 25 years after the study has finished.

LSTM will collect information about you for this research study from you and/or your GP records. We will use this information to confirm your eligibility and for the purposes of our research. This will not affect your care and will not be used to make decisions about future services available to you, such as insurance.

Preventing Pneumo 2

Preventing pneumococcal disease through vaccination

Consent Form

Apply participant study number label

Please initial the box if you agree with each statement. Then, print and sign and date below.

I have read and understood the information leaflet **version** _____ **dated** __/___/____ for the above study. I confirm that the study procedures and information have been explained to me. I have been able to consider the information, had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	Initial
I understand that this study is voluntary and that I am free to withdraw without giving any reason and without affecting my medical care or legal rights.	Initial
I have received and will read the attached patient information leaflets for the PCV-13 and PPV-23 vaccines, which I may receive as a part of my participation in this study.	Initial
I agree that the research team may share, use and store my personal information as described in this information leaflet.	Initial
I understand that relevant sections of my medical notes and data collected may be looked at by individuals from the study team, the LSTM (Sponsor), regulatory authorities or Liverpool University Hospitals NHS Foundation Trust, where it is relevant to my taking part in this research. I give permission for these people to access my records.	Initial
I agree to my GP being informed of my participation. I agree that my GP can provide the research team with information on my medical history and/or the researcher can access my electronic medical records relevant to my participation in this study if required.	Initial
I agree to my samples being collected, used and stored as described in this information leaflet.	Initial
I agree that my anonymised data and samples can be transferred outside of the UK for the purposes of this study and other ethically approved studies, including being sent to Pfizer Inc. and other collaborators.	Initial
I understand that some of my samples will be used to investigate genetic factors affecting infection and immunity.	Initial
I gift my samples to be used for future ethically approved research in the UK and overseas. I understand that my samples are anonymised and will be transferred to a research tissue bank at the end of the study. I agree that my samples may be used in future research to investigate genetic factors affecting infection and immunity.	Initial
I give permission for the study team to store my contact details in order to invite me to participate in future research.	Initial
Females of childbearing potential only: I confirm that I am not planning to conceive, and I will use effective contraception during the study.	Initial NA ☐
I give permission for the study team to register my details on The Over-volunteering Prevention System (TOPS) database.	Initial
I voluntarily agree to take part in this study.	Initial

_____	_____	_ _/_ _ _/_ _ _ _
Name of participant (print)	Signature	Date *(dd-Mon-YYYY)*
_____	_____	_ _/_ _ _/_ _ _ _
Name of person taking consent	Signature	Date *(dd-Mon-YYYY)*

Original – Investigator Site File, 2 Copies – Participant, Medical Notes