Liverpool University Hospitals
NHS Foundation Trust

Research & Development Directorate
University Hospital Aintree
Room 2.06, Clinical Sciences Centre
Liverpool
L9 7AL

Hospital Acquired Pneumonia Observational Study of Sputum (HAPOSS)

Participant Information Sheet

We would like to invite you to take part in our research study. Before you decide you should understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. One of our team will go through the information sheet with you and answer any questions you have.

What is the purpose of the study?

Pneumonia is an infection of the lungs which can be caused by a number of different bacteria and viruses. When pneumonia occurs in hospital it is called Hospital Acquired Pneumonia (HAP). Normally if the doctor thinks you have HAP then they will try to obtain a sputum sample from you to send to the microbiology lab to work our which germs (bacteria or viruses) are responsible. However, because the microbiology tests take several days to produce results, in the meantime the doctor starts you on antibiotics designed to kill a range of possible causes. However, these starting antibiotics are based on a best-guess as to the likely cause and sometimes we get the guess wrong and they don't work. Moreover, the antibiotics we choose as starting treatment for HAP can lead to complications.

Ideally our first choice antibiotic would be the right one and would be based on a knowledge of the bacteria causing the HAP. We now have a new test that might enable us to determine the cause of HAP quick enough to guide this initial choice of antibiotic. However, before we roll this new test out we need some information about the range of bacteria it is likely to identify in patients with HAP. This will enable us the design a new antibiotic protocol to help doctors chose antibiotics based on the results of the new test.

The aim of this study is to establish the range of bacteria seen in HAP and to use this to modify our antibiotic guidelines for future patients.

Why have I been invited to take part?

For this study we aim to test 100 sputum samples from patients diagnosed with HAP. Our research team works with the doctors and nurses on the ward. You have been invited to take part because the doctors looking after you think you have HAP and have analysed a small amount of the sputum you have in the new machine. We would like to analyse those sputum results and add the data from your sample to our database.

Do I have to take part?

It is up to you to decide on whether to join the study once you understand what it involves. If you agree to take part we will ask you to sign a consent form. You are free to withdraw at any time without giving a reason. This would not affect the standard of care you receive. You will be able to choose if the information collected up to that point may be used or should be destroyed.

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What will I have to do?

This research study involves gathering information about you your sputum sample. If you agree to take part in this study, you will not need to be seen again as all the information required is standard information available from the medical record.

What will happen to me if I take part?

The research study will run alongside your routine hospital care and you will not need to spend any longer in hospital than normal. Soon after your diagnosis of pneumonia a member of the research team will review your medical notes and retrieve the information we require.

What are the possible disadvantages of taking part?

There are no disadvantages other than allowing the research team to store anonymous information about your medical conditions and your sputum sample.

What are the possible benefits of taking part?

The study is unlikely to directly benefit you directly but your participation will help similar patients in the future.

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

Taking part in the study is entirely voluntary. You are free to withdraw at any time and do not have to give a reason for this. This will have no effect on your medical care now or in the future.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you wish to complain formally, you can do this by contacting the Research Governance office at Aintree University Hospital. The contact person is Mrs Michelle Mossa 0151 529 5871.

Will my taking part in this study be kept confidential?

All information which is collected about you will be kept strictly confidential. It will be stored securely within the Hospital and University of Liverpool systems. Access to your personal information collected in the study will be restricted to authorised research staff only.

What will happen to the samples that I give?

A small (less than half a milliliter) sub-sample of the sputum sample you gave was analysed in a new machine which can rapidly determine which bacteria and viruses are present. The rest of the sample was sent, in usual way for the usual microbiological tests in the NHS microbiology laboratory. The NHS laboratory will handle and dispose of your sputum sample in the usual way. No samples are retained.

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What will happen to the results of the research study?
At the end of the study, we create reports of our findings and share these with the scientific community. This will be a summary of all participants' results and it will not be possible to derive any specific information about your tests from this. The results of this research study will help in the design of the next phase of research aimed at evaluating the new diagnostic tests for HAP.

Who is funding the research?
This study is jointly funded by a grant from the University of Liverpool and by the provision of test kits and the loan of machines by the test manufacturers, bioMérieux.

Who has reviewed the study?
The scientific components of this study have been reviewed by member of the University of Liverpool and an independent expert at the Liverpool School of Tropical Medicine. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests.

How will we use information about you?
We will need to use information from you and your medical records for this research project.
This information will include your hospital number and your name. People will use this information to do the research or to check your records to make sure that the research is being done properly.
People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?
You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
by asking one of the research team

Further information and contact details
If you have any further questions please contact either of the following members of the research team during normal working hours.

Dr Dan Wootton (Study Chief Investigator and Principle Investigator Aintree Hospital)
Tel: 0151 529 3796 Email: dwootton@liverpool.ac.uk

Dr Victoria Price (Principle Investigator, Royal Liverpool Hospital)
Tel: 0151 706 3623, or 0151 706 3401 Email: Vicky.Price@rlbuht.nhs.uk