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**PANTHER**

**Patient Information Sheet Summary**

## Precision medicine Adaptive Network platform Trial in Hypoxaemic acutE respiratory failure

We are inviting critically ill adults who have been admitted to the intensive care unit (ICU). We are studying people who need organ support, such as with their lungs or heart with conditions such as Acute Respiratory Distress Syndrome (ARDS) or during a pandemic to participate. ARDS is a severe lung problem that makes it hard to breathe because there is too much fluid in the lungs. We know critically ill patients can be split into different subgroups called hypoinflammatory and hyperinflmmatory. We want to be able to identify which patient subgroups will respond best to a treatment in order to improve patient care.

This form provides information on the study and the treatments we are using.

Please take time to read the following information carefully and do talk about it with other people if you would like to. Ask us if there is anything that you do not understand or if you would like more information. You can take time to think about your participation.

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# WHAT TReatments are being tested?

We are testing treatments in patients who have been admitted to an ICU. Simvastatin and Baricitinib are treatments being compared against usual care for critically ill adults who need organ support. You will receive one of the treatments below or the standard of care if you decide to participate. Further information on the treatments within this trial are provided below:

**Simvastatin**

Statins are commonly used to lower cholesterol and lower the risks of heart attacks or strokes. One of these drugs, simvastatin may help repair the lungs by reducing inflammation and repairing blood vessels in the lungs, therefore may be beneficial to treat critically ill adults who need organ support. This will be given for up to 28 days or up until you leave the ICU.

**Baricitinib**

Baricitinib is a medication used for arthritis. It reduces swelling and may also help repair the lungs by reducing inflammation. This will be given for 10 days or up until you leave the ICU.

*Both treatments are given as tablets to swallow. If you are unable to swallow, it will be given via a tube.*



**Usual Care**

This will be the usual care provided at your local hospital.

Not all treatments may be available at your hospital, your doctor will be able to tell you which treatments are available and best suited to you. These treatment options listed above also include a ‘standard care’. A computer randomly selects which treatment options you will receive. This means you may not receive any of these treatments, even if you choose to participate in the PANTHER trial. How patients recover over time is then compared between the different treatment options to work out which treatments are best.

# Which treatments WILL i receive?

Your doctor will decide whether you are suitable to participate in all or part of this trial.

# What else will I need to do?

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**Nasal Swab & Lung Secretion Test**

A nasal swab will be taken to find out whether you have any infections. Some participants will have secretions (tracheal aspirate) collected from the lungs. This is done with a small suction tube called a catheter. It is passed through a breathing tube and is part of your usual ICU care with the goal of keeping the lungs clear of secretions to help you breathe better.

These secretions are usually thrown away, but we will keep a small sample if you agree to take part in the study.

**Blood Test**

To know whether you are in the hypoinflammatory or hyperinflammatory group, we will take a blood sample.

So that we can understand more about how the treatments in this study work, we will collect additional blood samples Once you have been randomised, depending on the treatment, a second blood sample will be taken. Blood samples will also be collected 3 and 7 days later (about 2 tablespoons total). Blood samples will usually be taken either via a line already in place or using a needle.

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Lung Fluid Test

We may also take a fluid sample from your lungs. This procedure is called a Bronchoalveolar Lavage (BAL). This will happen before you are randomised. Fluid samples will then be collected 3 and 7 days later. This involves putting a thin flexible tube (bronchoscope) through your nose or mouth down into your lungs. This tube allows the team looking after you to see inside your lungs. Once in the right place, a small amount of saltwater will be poured into the lung and collected. This helps us to know whether the treatment is working. This is a well-recognised safe procedure often undertaken in ICU to look at lung inflammation. Extra sedation may be used and some local anaesthetic may be used to make the procedure is comfortable if needed. This procedure can rarely be associated with a fall in oxygen levels. Prior to inserting the bronchoscope the amount of oxygen will be increased and we will closely monitor these levels during the test. The test will be stopped if the oxygen level falls significantly. This will not be performed if the consultant in charge of the ICU has any concerns whatsoever and will only take place if you are already receiving breathing support (called ventilation) via a breathing tube in the lungs.

**Lung Fluid Test**

So that we can treat patients as quickly as possible some of these treatments may already have started, you do have the option to stop these if you prefer to do so.

Before you leave the hospital, we will ask you to complete some exercises and ask you some questions to see how well you can move around and how well you are able to understand and remember things. We’ll also find out how they are doing. We will also collect data from your hospital records and other NHS linked data.

Once your treatment has finished, we may contact you at 3 and 6 months after you started in the trial with a telephone call or email to ask about your quality of life and wellbeing using questionnaires to check how you are doing. We may also collect this information using an electronic link (optional).

Participation in the PANTHER trial is voluntary. All patients, including those that do not wish to participate in PANTHER, will receive the best standard of care available at this hospital.

More detailed information about the study including how we use patient data and privacy, legalities and insurance of the study, risks and benefits, how to make a complaint and how to find out the results of the study can be found in our full patient information sheet and privacy notice. (A written copy is available or is available online at [www.panthertrial.org.uk/patients](http://www.panthertrial.org.uk/patients) )

# Site Contact Information

Investigator name:-

Site Contact details:-

Study Contact Information

Please contact The PANTHER Trial team using the following contact details:

Name: The PANTHER Trial Team

Telephone number: 0207 5949725 available during UK working hours Mon-Fri 09:00-17:00

Email: pantheruk@imperial.ac.uk

Website: [www.panthertrial.org.uk](http://www.panthertrial.org.uk)

Thank you very much for taking part in this study!

If you are happy to proceed, please complete the attached consent form.

A copy of the written information and signed Informed Consent form will be given to you to keep.

# Consent Form for Participants with Capacity and now recovered capacity

**Full Title of Project:** Precision medicine Adaptive Network platform Trial in Hypoxaemic acutE respiratory failuRe - **PANTHER**

|  |  |
| --- | --- |
| **Site number:** |  |
| **Patient Number:** |  |
| **Patient Name:** |  |
| **Name of Principal Investigator:** |  |

In the event that the patient has capacity but cannot write, please can a witness be present when completing this consent form.

**Please initial box**

|  |  |
| --- | --- |
| 1. I confirm that I have read and understand this document and have read/received a copy of the appropriate patient information sheet which includes a link to the privacy notice for **PANTHER.** |  |
| 1. I confirm I am happy to consent to participate in the trial with the following treatments: Simvastatin, Baricitinib   (*delete treatments site is not participating in and strikethrough treatment if patient does not agree)* |  |
| 1. I confirm that I understand the **PANTHER** study and I have had the opportunity to ask questions which have been answered fully. |  |
| 1. I understand that my participation is voluntary, and I am free to withdraw at any time, without giving any reason and without my legal rights nor treatment / healthcare being affected. |  |
| 1. I understand that sections of any of my medical notes and other personal data generated during the study may be looked at by responsible individuals from and working on behalf of Imperial College London, by representatives of regulatory authorities, ICNARC, NHS Digital, SICSAG, from the NHS Trust where it is relevant to my taking part in this research. |  |
| 1. I give consent for information collected about me to be used to support other research or in the development of a new test, medication, medical device or treatment by an academic institution or commercial company in the future, including those outside of the United Kingdom (which Imperial has ensured will keep this information secure). |  |
| 1. I give consent for samples (bloods, nasal swab, lung secretions and fluids) collected about me to be used to support other research or in the development of a new test, medication, medical device or treatment by an academic institution or commercial company in the future, including those outside of the United Kingdom (which Imperial has ensured will keep this information secure). |  |
| 1. I understand that tissue samples (bloods, nasal swab, lung secretions and fluids) and/or data collected from me are a gift donated to the research team and that I will not personally benefit financially if this research leads to an invention and/or the successful development of a new test, medication treatment, product or service. |  |
| 1. I agree to my tissue samples (bloods, nasal swab, lung secretions and fluids) being used to undertake genetic research which may have the potential to generate data that can be tracked back to me |  |
| 1. I give consent to being contacted about the possibility to take part in other research studies. |  |
| 1. I consent to allow the use of data already collected in the trial, as well as ongoing data collection and follow up information to be obtained from my medical records up to 12 months after my inclusion. |  |
| 1. I agree to my GP being informed about my participation in this research study and any incidental findings to be conveyed to them (Optional). |  |
| 1. I understand I will be contacted by my local hospital or the study team in 3 and 6 months to ask about my quality of life and wellbeing.   *(if you agree to this statement provide your details below and tick your preferred contact method ).*  *Phone Email* |  |
| 1. I would like to be informed of the PANTHER study results when these are available.   *(if you agree to this statement provide your details below).* |  |
| 1. I consent to take part in **PANTHER** |  |

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| Telephone number: |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Email address: |  | | | | | | | | | | | |  | |
| Postal address: |  | | | | | | | | | | | | | |

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Name of patient Signature Date

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Name of staff member Signature Date

*(Listed on delegation log)*

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Name of Witness Signature Date

*(To be used if patient cannot write*

*e.g. due to weakness)*

*(Independent of PANTHER study team)*

The original is stored in the study site file, 1 copy for participant;

1 copy for hospital notes