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**PANTHER**

Patient Information Sheet

## 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) with certain conditions to be part of our research study. 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. We can identify these subgroups by measuring certain substances in the blood. Patients from each subgroup may respond differently to some treatments. We want to be able to identify which patients will respond best to a treatment in order to improve patient care. During a pandemic, subgroups may not be identified as we will not know enough about the new disease. This form provides information on the study, the treatments we are using, and risks and benefits of taking part.

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. Thank you for reading this.

# What is the purpose of panther?

Research trials aim to find out what the best treatments are for patients. PANTHER is the name of this research trial, which is looking at treatments for critically ill adults who need support for their organs to work (organ support). These conditions can be life-threatening and are treated in hospital, they are usually a complication of other serious conditions. There are no proven medicines to treat critically ill patients who need organ support. We have discovered two subgroups of patients, called “hyperinflammatory” and “hyopinflammatory”, and one of these may react better to different treatments. Inflammation is a natural process that helps our body fight off harmful substances like infections*.* In this trial we want to know which treatments are best for the different subgroups of patients.

We are encouraging people from all backgrounds and ethnicities to take part in the study. In previous studies, people from Asian, Black and minority ethnic communities, and people with lower incomes, have not been well represented in research studies. This has meant that new discoveries have not helped everyone equally.

# 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.

# Why have I been chosen?

This study is taking place in hospitals around the world. You have been asked to take part in this study because you are critically ill and on organ support in an intensive care unit. We know that treating these patients early provides the best chance for treatments to work. So, we need to include patients as soon as possible once they develop the condition, so some of the treatments may already have started before you were given this consent form. If you were not able to give your consent straight away, we will ask your family member/friend or treating doctor for their consent to include you in the study and then we will check if you are happy to continue once you are able to give your consent.

# dO i HAVE TO TAKE PART?

You do not have to take part and you can decide if you want to take part or not. It will not make a difference to the standard healthcare you receive, if you do or do not take part.

If you do want to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you change your mind later, you can stop being part of the trial at any time without giving a reason.

# Which treatments will I receive?

Your doctor will decide whether you are suitable for the treatments in this trial. You will be allocated treatments in these trials by a ‘randomisation’ process. Randomisation is a process that is like tossing a coin and means people are put into groups by chance rather than chosen for each group. This helps us compare very similar groups of patients to see which way of treating patients is the best. The groups are selected by a computer which has no information about the individual. If you are randomised to receive a treatment you may receive this via a tablet or a tube if you are very unwell. The doctor or researcher will explain the study to you, but neither they nor you can decide on the treatment allocation.

# 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 the participant has 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). Blood samples will usually be taken either via a line already in place or using a needle.

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A blue circle with white lungs in it

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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**

These samples will be sent to a central laboratory for storage. The samples will be stored without your name included on it, only a code, will be held securely, and no attempts will be made to identify you from it. Samples are always stored according to appropriate regulations.

We are also asking whether you are happy for these samples collected during the study can be stored indefinitely and used for further ethically approved research projects as required. Future tests may involve genetic analysis. We may share samples with other investigators or commercial organisations in the UK or internationally, to help understand critical illness and improve treatments in the future. If this happens, where possible, the samples shared would be anonymous and external investigators or organisations would not be able to identify you. The anonymised data collected as part of the study may also be used to understand the sample analyses with your permission

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 you are doing. A researcher will collect data about you for the study.

We will contact your GP to let them know about your participation in the study. Once your treatment is 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). This helps us to see the longer-term effects of the treatments. The questionnaires will take about 40 minutes to complete. Taking part in these questionnaires is optional, so you can still take part in the study in hospital even if you do not want to answer these questionnaires. If you feel too unwell to do this then a family member, friend or caregiver can help to complete them on your behalf. Ideally, please ask the same person to help each time.

To ensure we can learn the effects of the study treatment we will collect information about you from your medical records until 1 year after your inclusion in the study; this includes information before and after your inclusion. Some of the data collected for the study are already collected as part of your daily and ongoing medical care. With your permission, we will use this routinely collected data held by the Intensive Care National Health Audit & Research Centre (ICNARC), NHS Digital, UK Health Security Agency, genetic and other research databases (if you have provided your information/samples to them). We will keep this information for at least 10 years after your discharge. All your data that has been collected will be pseudonymised, which means that your data will be allocated a reference number and so you cannot be directly identified by this.

If you do not wish to be part of this study, no further information will be collected about you for the trial and the doctors will continue to provide you with whatever medical treatment is needed.

# What are the side effects of any treatment received when taking part in this research?

All medical treatments can cause side effects. The risks from side effects are similar if you choose not to be in the study as you will be having many different treatments for critically ill adults with organ support as part of your standard healthcare. Your doctor will be aware that you are taking part in the study, and so the doctors will be looking out for any side effects which may be because of the trial treatments.

**Simvastatin**

Simvastatin is a medicine used to lower cholesterol and the risks of heart attacks or strokes. Simvastatin may have the following main side effects including muscle aches, pains, tenderness or weakness, and temporary changes in muscle and liver blood tests.

**Baricitinib**

Barcitinib is a medicine used for arthritis. Barcitinib may have the following main side effects including an increased risk of infections, as well as temporary changes in blood counts, cholesterol, muscle and liver blood tests. Very uncommon side effects include a risk of blood clots in the legs or the lungs (deep vein thrombosis, pulmonary embolism) and issues with the large bowel which can lead to damage to the bowel (diverticulitis). These effects are more likely to occur in those patients who are taking baricitinib for a long period of time such as months or years. Where baricitinib is being given for a period of days as in this study, these effects are less likely to occur.

# Are there any other risks of taking part?

When our team contact you by phone at 3 and 6 months after you are included in the study, some patients might find discussing their ICU experience distressing. We can refer you to your GP if you need any further help. The person from our team who will speak with you will be aware of this and will conduct the questionnaires respectfully and appropriately. They will aim to reassure you and put you at ease and can direct you to the right team if you need additional support. You may also have a friend or family member present for the questionnaires to help answer the questions or for general support. You can stop answering the questions if you want to or take a break and come back to them another time.

The researcher will treat your information with respect and in line with the highest standards of confidentiality and security. The information we collect about you will be non-identifiable, you will be assigned a patient number.

# Pregnancy

Women who are pregnant will not be included in the study if the treatment is not known to be safe for them.

# What are the possible benefits of taking part?

You may not benefit directly from this study, but the results may help future patients and assist doctors in the future in treating critically ill adults who need organ support more effectively and successfully. If, during the study your doctor becomes aware of a condition to which you were unaware, your doctor will discuss treatment options with you as per your usual standard of care.

# Will I be paid for taking part?

There is no payment for taking part in this research trial.

# How will my information be looked after?

All data (information about you from this trial) will be kept private by the study team in a correct, confidential, and secure manner. The study will follow UK and EU regulations to make sure your data is protected. The only people allowed to look at your information will be the doctors running the study and authorised staff at Imperial College London. A privacy notice on the study is available from your hospital or on the study website: - [www.panthertrial.org.uk/patient](http://www.panthertrial.org.uk/patient)

# What happens when the research study stops?

Your involvement with this research stops once you have completed your 6 month follow up telephone conversation with a member of the clinical research team. You will continue to receive the standard care available from your hospital if you need more treatment.

# What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Insert name and contact details). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance, and Integrity Team.

# What will happen to the results of the research study?

The results of this study will be presented at medical meetings and published in scientific medical journals. Only anonymous group information and no personal information will be presented so you will not be identified as being involved with this research. If you are interested in the results, you will be able to look them up after the study has finished on our study website: - [www.panthertrial.org](http://www.panthertrial.org) and the [HRA website.](https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/) If you would like a copy of the results please do let us know by initialling the point on the consent form below.

# Who is organising and funding the research?

This study is being organised and sponsored by Imperial College London and the Chief Investigator is Professor Danny McAuley. It is funded by the National Institute for Health and Care Research (NIHR) in the UK.

# Who has reviewed the study?

This study was allowed to go ahead after being approved by the Research Ethics Committee having given a favourable ethical opinion for conduct in the NHS by the North West - Liverpool Central REC and the MHRA (Medicines and Healthcare products Regulatory Agency).

# Who can I contact for independent research information?

***England/Wales sites only***

If you have any questions about being in a research study, you can contact the Trust’s Patient Advice Liaison Service (PALS). They will give you advice about who you can talk to for independent advice.

|  |  |
| --- | --- |
| **Local PALS office telephone number** | **Local PALS office address** |
|  |  |

***Northern Ireland sites only***

If you have any questions about being in a research study, you can contact the person listed below. They will give you advice about who you can talk to for independent advice.

|  |  |
| --- | --- |
| **Local Contact** | **Local address** |
|  |  |

***Scotland sites only***

If you have any questions about being in a research study, you can contact [*insert full name*] (contact details below) who is not involved in the study and will be able to give you independent advice.

[*insert independent contact telephone number/email address/postal address*]

# 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 would like to join patient events and keep in touch with the PANTHER Team, please scan the QR code below.**

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

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# Consent Form for Participants with Capacity or 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:** |  |

**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

*(Independent of PANTHER study team)*

*(To be used if patient cannot write*

*e.g. due to weakness)*

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

1 copy for hospital notes