

SHEFFIELD PULMONARY VASCULAR DISEASE UNIT

Patient Research Passport



Your guide to getting involved in clinical research





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The Sheffield Pulmonary Vascular Disease Unit at the Royal Hallamshire Hospital is one of the largest pulmonary hypertension treatment centres in Europe. A dedicated clinical team provides care for more than

1700 PATIENTS

from across Yorkshire & the Humber, the Midlands, the North West and Wales.

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This booklet provides an introduction to clinical research, why it is important for people with pulmonary hypertension, and how you could get involved. If you participate in any of our research, please bring this booklet with you every time you visit the Sheffield Pulmonary Vascular Disease Unit.



What is clinical research?

Clinical research is the process we use to generate new knowledge and better understanding of health, illness and its treatment. We can use the evidence from research to improve the treatment of people with pulmonary hypertension and other conditions. In turn, the medical advances we make through research will hopefully improve the quality of life for patients in the future. All of the UK Pulmonary Hypertension treatment centres in NHS hospitals are involved in research. We use a number of different approaches to clinical research:

Clinical trials: a clinical trial is an assessment of a new drug or medical procedure. In drug trials, the new drug is often compared with a dummy drug ('placebo'). Some patients will receive the real drug and some will receive the placebo, but they won't find out which until the end of the trial. This method helps to show if the new drug really is being effective or not.

There are other types of research which study new methods of diagnosing and assessing medical conditions – for example testing out new kinds of imaging scans; or analysing the results of breathing tests.

Questionnaires and interviews: research may focus on the opinions and experiences of patients, their families, and health professionals, which can help

clinicians and patients to make better decisions about managing a patient's condition.

Using blood and tissue: some studies require that a patient provides blood or tissue samples. These can be analysed to answer questions about the biology of how diseases develop, and how our genes influence our health. Through this type of research we aim to find new drugs for treating pulmonary hypertension.

'Data-only' research: this type of research uses only the clinical information and test results that have been recorded during patients' clinical care. Usually this will not require the patient to do anything other than attend their normal hospital visits.

Health services research: looks into ways in which hospital teams and health services can be organised to make them more effective, so that resources are used more efficiently to improve the experience and outcome for patients and their families.

Why is clinical research important?

In the UK, before a new drug can be given to patients, it must be shown to be safe and effective in clinical trials, and must be approved by the MHRA

(the Medicines & Healthcare Products Regulatory Agency). For people with pulmonary hypertension, clinical trials have transformed medical treatment. Before there were therapies available to treat PH, people diagnosed with the condition had an average life expectancy of about 3 years. Now, thanks to the approval of various new drugs, this life expectancy is much improved. Without clinical trials, and the people who agreed to be involved in them, these drugs would not be available.

PH is also a relatively rare disease. This means that it may be difficult for pharmaceutical companies to get enough people involved in clinical trials for PH.

Clinical research also helps to:

- Detect or diagnose illnesses by developing new scans or blood tests;
- Treat illnesses by testing new or existing medicines;
- Find out how people can control their symptoms or improve their quality of life;
- Find out how best to provide psychological support.



CHRISTINE SHARES HER EXPERIENCE OF A CLINICAL TRIAL

Christine has had PH for 5 years. She said:

“ I had been taking warfarin and a diuretic for my PH for about a year, but it was getting slightly worse and I was keen to try something new. My consultant explained the next step would be to start me on Bosentan (Tracleer). He explained that some people have problems with Bosentan affecting their liver. He let me know there was a clinical trial running to test a similar drug. He said it might not affect people's liver function as much as Bosentan.

My consultant explained that I might get a 'dummy' drug rather than the study drug. The study lasted 3 months, and I had to attend the clinic at the start and the end. Although the visits took slightly longer than normal, I am still pleased that I took part.

My PH didn't change much over the 12 weeks. However, I learned that the drug being tested has been approved to treat PH. I'm pleased to have helped give another treatment option to someone who might not be able to take Bosentan. I like to think that in my small way I helped to get that drug approved.”

Clinical Research in the Sheffield Pulmonary Vascular Disease Unit

The Sheffield Pulmonary Vascular Disease Unit (PVDU) at the Royal Hallamshire Hospital is one of the largest pulmonary hypertension treatment centres in Europe. A dedicated clinical team provides care for over 1700 patients from across Yorkshire and the Humber, the Midlands, the North West and Wales. As well as providing specialist clinical care, we have developed a programme of clinical research through our collaboration with the University of Sheffield and partners in pulmonary hypertension centres around the UK.

Our key research themes are:

Clinical trials of new drugs and medical devices

In Sheffield we undertake a number of clinical trials which play a very important role in the development of new treatments. In recent years we have been involved in trials of drugs which have since become established treatments for many PH patients, such as Ambrisentan, Sildenafil and Trepostinil.

Sheffield Teaching Hospitals is also the first UK site to test a new technique called 'pulmonary artery denervation'. This treatment uses ultrasound energy to deactivate some of the nerves affecting blood flow to the lungs, which is hoped to lead to reduced blood pressure, improved heart function, exercise

capacity, and wellbeing for the patient.

Lung and cardiac imaging

The Sheffield PVDU works closely with the University of Sheffield POLARIS (Pulmonary, Lung and Respiratory Imaging Sheffield) group, who have developed a new technique called hyperpolarised gas magnetic resonance imaging (MRI). By using this technique doctors can see accurate images of the lungs and heart to know how well they are working. This can help to make a faster and more accurate diagnosis of a patient's condition. The POLARIS team have secured funding to develop these techniques so they can be used in the clinical care of patients with PH and other lung conditions.

Our unit also collaborates with the **Sheffield INSIGNEO Institute for in silico Medicine** which brings together engineers, scientists and doctors to use computational modelling to improve our understanding of pulmonary hypertension.



Biobanks and discovery science

In collaboration with the University of Sheffield Pulmonary Vascular Research Group, we have developed the Sheffield Pulmonary Hypertension Biobank. Hundreds of patients have provided samples of their blood and DNA, which are analysed and stored for future research. This resource helps us to carry out research into different types of pulmonary hypertension, how it is affected by our genetic make-up, and how the disease develops at a cellular and molecular level. The hope is that if we can identify key molecules and develop new drugs that block their activity, then we may be able to slow down the progression of disease - or hopefully even eventually reverse it.

The Sheffield PVDU is also part of a research network of the National Pulmonary Hypertension Centres of UK and Ireland. The National Cohort Study of Pulmonary Arterial Hypertension (PAH) aims to recruit patients and their family members from around the UK over a 5 year period, to provide information about how genes affect the way people respond to treatment. We also hope to learn what environmental triggers might be involved in PAH. The information will allow us to provide families with better estimates of their risk of developing PAH, and identify new types of treatment.

Qualitative research, patient-reported outcomes and medical humanities

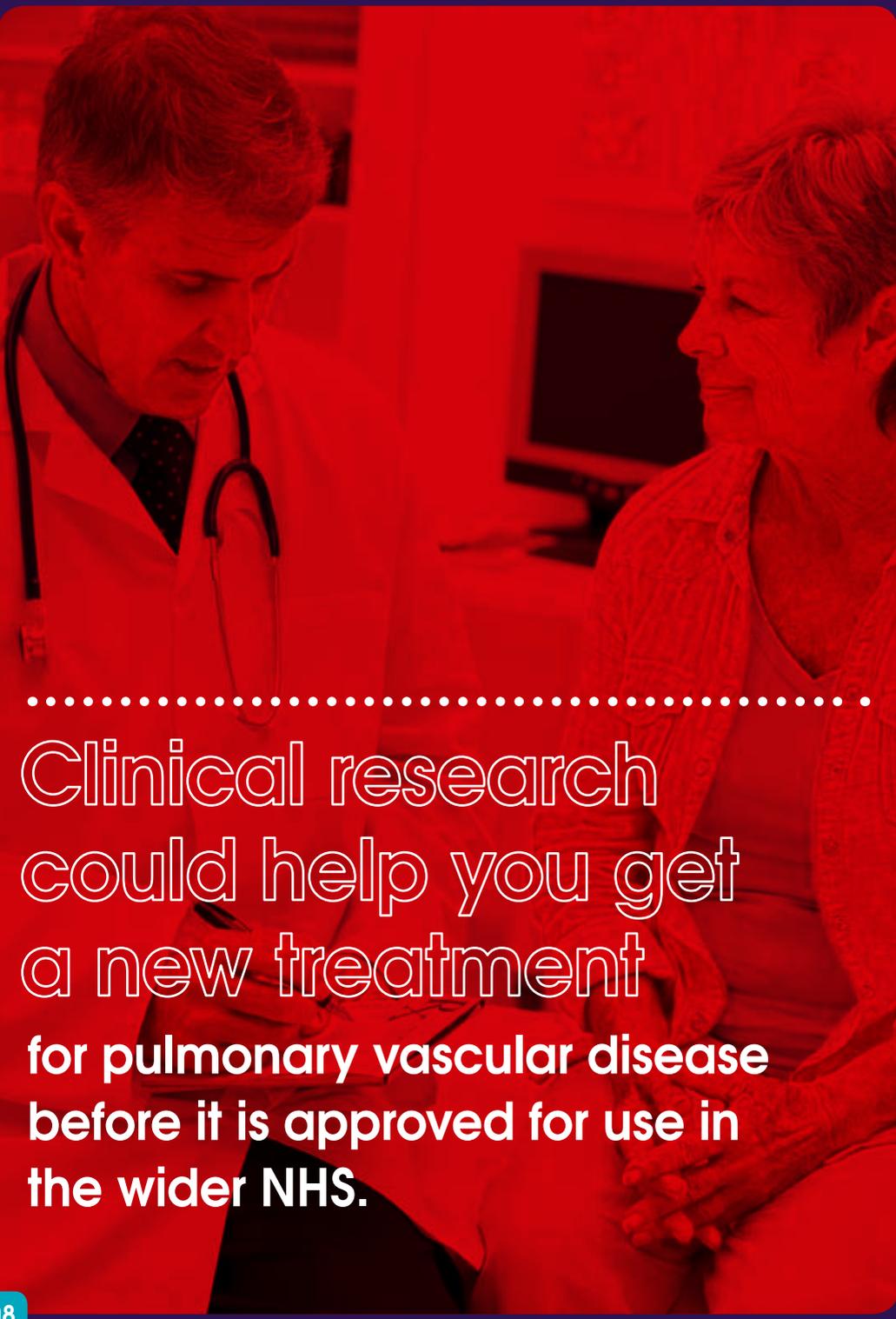
We are committed to trying to understand more about the patient journey using qualitative research

methods. We hope that by doing so we will be better able to meet the needs of patients and their families and improve their quality of life. Work by the Sheffield PVDU in collaboration with the Pulmonary Hypertension Association UK has led to the development of a patient questionnaire ('Emphasis-10'), which can be used by health professionals to help measure and understand patient experiences. The Emphasis-10 document is freely available and used throughout the UK, and has been translated into several languages.

Medical Humanities Sheffield is a collaboration of groups from the arts, science and medicine, to explore how illness impacts on patients and their families, and how history and cultural views influence our approach to PH and its treatment. The group promotes links with artists through developing artist-in-residence programmes, and is undertaking research to explore how PH changes the lives of patients, relatives and carers.

Safe and ethical research

Before clinical research can begin, it is reviewed by an independent research ethics committee to ensure that patient's rights, safety and wellbeing are protected. At a local level, every research study is approved by the Sheffield Teaching Hospitals R&D department which ensures that the research team have the right facilities, and have had appropriate training to run the research safely and effectively.



Clinical research could help you get a new treatment for pulmonary vascular disease before it is approved for use in the wider NHS.

Why should I participate in clinical research?

Clinical research could help you get a new treatment for pulmonary vascular disease before it is approved for use in the wider NHS. However, there is also a chance that the new treatment turns out to be no better than the standard treatment. Either way, by participating you will be helping to improve medical advances in the treatment of disease.

Participating in research may require some commitment of time and effort from yourself and so you should think carefully about it, and discuss it with your family and friends. But we believe all of our research studies are important and the volunteers who participate are making a vital contribution to clinical research, which is greatly appreciated.

Each study is different and patients can be involved in different ways.

For example:

- Some studies ask only if they can use the clinical information that you have already given in your routine hospital appointments – for example the results of your breathing tests or MRI scan if you've had one.
- Alternatively, some studies might require you to provide an extra sample of blood, or answer a questionnaire.
- At the other end of the spectrum, some clinical trials might need you to make several additional visits to the hospital and have extra tests and scans to measure the effects of the new drug you are taking in the trial.



How can I be involved?

At the Sheffield Pulmonary Vascular Disease Unit, we believe it is important to think about clinical research alongside the day to day activities of patient care. When you come for a visit to the hospital it is possible that one of the hospital team (usually a doctor or a research nurse) will talk to you about research studies in which you could be eligible to participate. At other times we might send you a letter in the post to let you know about research.

If we think you are eligible for one of our studies you'll be given some printed information to read which should help you to decide whether or not you want to take part. The decision is always yours.

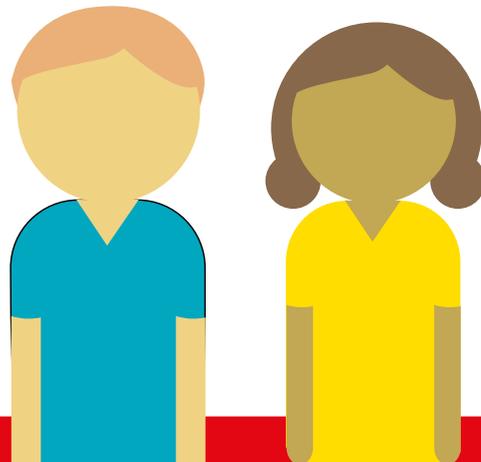
Here are some things to think about before you enrol in a clinical research study:

- Your PH may improve during a clinical trial, but it may stay the same. As with any treatment, you can't be sure of the outcome.
- In clinical trials of a new treatment, it is possible you'll experience unexpected side effects.
- You may be given a placebo during the trial and not the drug being tested.
- The number of clinic visits may be more than the amount of times you normally attend.

What questions should I ask?

Here are some of the key questions that you may want to consider before agreeing to take part in research:

- How long will the study last, and how much of my time will be needed?
- Will the costs of my travel, and other expenses, be covered?
- What are the possible side effects of taking a new treatment?
- Will I have to take extra tests, complete questionnaires or keep a diary?
- What would happen if something went wrong? (It's rare for patients to be harmed by research treatments, but you may want to ask about compensation arrangements if this were to happen.)
- Who can I contact if I have a query about being in the study?



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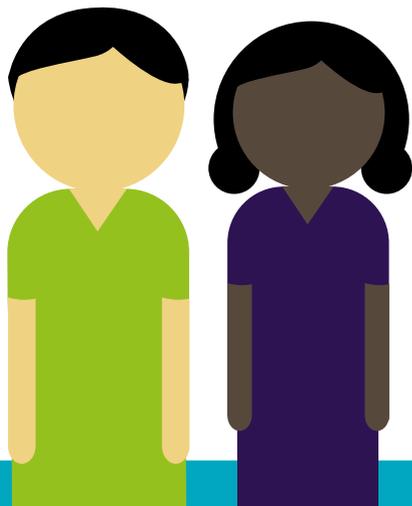
help you
to decide

Meet the clinical research team

If you get involved in a clinical research study, here are some of the hospital and university staff who you could meet in the research pathway.

Principal investigator

The principal investigator is the individual with overall responsibility for the conduct of the research in the hospital. For drug trials the principal investigator is usually one of the consultants or doctors in the pulmonary hypertension department. The consultant has the responsibility of reviewing your medical condition during the research to make sure it is safe for you to participate in the study.



Research nurse

The research nurse will usually be your main point of contact when you visit the hospital to take part in a research study. Research nurses organise the day-to-day running of the research. The research nurse will help to explain the research procedures to you and will be there to guide you during the research activity. This could include taking blood samples and other measurements, explaining questionnaires, performing walking or breathing tests, and administering new drugs or treatments in a trial. In Sheffield, we have a number of specialist research nurses who work as part of a team based in the Sheffield Clinical Research Facility (CRF) on O Floor of the Royal Hallamshire Hospital. The CRF has rooms and facilities especially provided for research, and some of your study visits might take place there.

Imaging technicians and radiographers

Some of our studies in Sheffield take images of our patients' lungs and heart using a specialised scanning technique called Magnetic Resonance Imaging (MRI). This takes place on C Floor of the Royal Hallamshire Hospital in the Department of Academic Radiology. The Academic Radiology investigators are developing new methods of looking at the lungs to be able to improve our understanding of disease and to make faster diagnosis. Other studies might involve you having an X-ray scan in the X-ray Department, also on C Floor of the Royal Hallamshire Hospital.



Respiratory physiologist

The staff in the Respiratory Physiology Unit are specialists in carrying out tests to measure your breathing and oxygen levels, and your ability to undertake exercise. These tests can involve walking up and down a corridor, on a treadmill or even a full 'cardio-pulmonary exercise test' using an exercise bike. Patients will often do some of these tests as part of their usual routine hospital appointments. Some clinical research studies also need patients to do extra respiratory tests, for example so that they can measure how much effect a new drug is having on your body.



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Our clinical research has enabled patients with Pulmonary Hypertension to access treatments that otherwise would not be available. This helps us give better care to the patients we see in Sheffield.”

Prof David Kiely

My Research Reminders

A member of the Sheffield Research Team will write notes in this section to remind you about the studies that you are involved in.

Please bring this booklet with you every time you visit the Sheffield Pulmonary Vascular Disease Unit.



Study Title

Principal Investigator

Research Nurse contact

Type of study, location, frequency of visits

My involvement

Start date / / End date / /

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For further information contact:

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or:

www.phauk.org
www.sheffieldclinicalresearch.org

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