



Dr Klaus Witte
Leeds Institute for Cardiovascular and Metabolic Medicine
The LIGHT Laboratories
University of Leeds
Leeds LS2 9JT

Participant Information Sheet

Chief Investigator: Dr. Klaus K Witte (Tel: 0113 392 6642)

Title: **Heart failure in Patients with Diabetes: cells, crosstalk and consequences**

IRAS project ID: **343489**

You are being asked to take part in a research study. Before deciding whether to participate in this study, it is important that you read and understand the following explanation of the proposed study procedures. The following information describes the purpose, procedures, benefits, discomforts, risks and precautions associated with this study. It also describes your right to refuse to participate or withdraw from the study at any time.

In order to decide whether you wish to participate in this research study, you should understand enough about its risks and benefits to be able to make an informed decision. This is known as the informed consent process. Please ask the study doctor or study staff to explain any words you don't understand. Make sure all your questions have been answered to your satisfaction before signing the consent form.

Part 1

Background to the study – heart failure

Chronic heart failure is a condition most people associate with a weakened heart. This is called heart failure with a reduced ejection fraction reflecting the reduced output of the heart with each beat. Most patients are comfortable at rest, but develop symptoms of breathlessness and fatigue during activity.

There are lots of people who have breathlessness and fatigue but without obvious heart muscle weakness. We call this heart failure with preserved ejection fraction reflecting that the pumping function looks preserved and it is likely that the problem is stiffness of the heart muscle so that blood cannot flow in as easily between each beat.

It is important to figure out which type of heart failure a person with breathlessness has because some tablets that work in one type do not work in the other. This implies that the causes of these two types of heart failure and their effects on the body might be different.

The interaction with diabetes mellitus

Diabetes mellitus is a condition where the cells of the body become resistant to the effects of insulin which lowers the body's capacity to cope with sugar. Amongst other effects, this changes the way all cells in the body make and use energy. This has widespread effects on the heart and arteries and can also lead to heart failure. People with diabetes mellitus are more prone to heart problems, but also can develop problems

with their kidneys, eyes and nerves. People with both types of heart failure who also have diabetes mellitus are also at much higher risk of hospital admission and other complications but we do not know why this is.

Communication within the body

The cells of the body and especially those of arteries, veins, muscles, fat and the heart seem to have developed a way to communicate with each other. This cell to cell communication is known as 'cross-talk'. We think that this cross-talk is abnormal in people with diabetes mellitus but also in people with heart failure.

Purpose of the study

We want to find out more about how the two different types of heart failure affect the rest of the body especially the muscles, the arteries and veins and the lungs to try and find out why the tablets we use for one type do not always work in the other. This will also help us begin to work out which tablets and treatments might be best for each type of heart failure. Overall, understanding the condition in more detail will also help find new treatments that could improve symptoms.

We also want to find out why diabetes mellitus is such a problem in people with heart failure and also how the cell to cell communication is disturbed and how that contributes to the way the two conditions (diabetes and heart failure interact).

Importance of the study

This study is important because rates of both heart failure and diabetes mellitus are increasing across the world and people who have both conditions together have a higher risk of problems. If we can find out the answers to some of these questions, it is possible that we can use medication to improve this.

Why have I been invited to take part?

We have invited you to take part in this study because your doctor has told you that you have diabetes mellitus. We would be grateful for your involvement whether or not you also have heart failure or other heart problems.

Briefly, the important aspects of this study for you, are that we will assess your heart's pumping function carefully and also assess your exercise capacity, your quality of life, your lung function and your hand strength. We will also do some blood tests. Many of these tests will be the same that we would do anyway to assess the heart and some you might have had done previously.

We will also ask you to consider some optional tests that involve taking some muscle and fat and measuring the nerve supply to the muscles. Also if you have a pacemaker already, we will ask if we can do the heart scan as we increase the heart rate.

Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. You will be given the opportunity to ask questions, but there are also telephone numbers at the end of this information sheet if you wish to call yourself. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen if I take part?

If you agree to participate in this study, we will invite you to come to the Clinical Research Facility on F-floor of the Leeds General Infirmary for about two hours. To save you a hospital visit, this appointment could be combined with a clinical visit.

If you agree to participate in one of the optional studies, we would ask you to come to the Research Unit on a second (or third) time.

Clinical assessment

At this first visit, which might last up to 2 hours, you will first be seen by a study nurse, study doctor or study cardiac physiologist who will ask you to sign the consent form. They will record what tablets you are taking, review with you any other illnesses including your past history of heart and other problems, and ask about your symptoms. The study team member will also confirm the information by looking at your medical records. They will measure your height and weight.

Quality of life and frailty scores

We will ask you to fill in two quality of life questionnaire at this point. Please answer the questions as completely and as honestly as possible. Team members will be there to help if you need it. During the visit, the nurse will also fill in assessment documents to record markers of frailty and weight loss. We will also ask you to answer some questions that help identify people who are developing forgetfulness. None of these questionnaires ask embarrassing questions.

Bioimpedance

We will ask you to stand on a special set of weighing scales and hold two hand grips to allow us to assess body composition. Essentially this device will measure the proportions of muscle and fat in your body. The measurement takes two minutes.

Handgrip strength

We will measure your handgrip strength. This is done using a small machine that you hold firmly in your palm. We will ask you to grip as tightly as you can for a few seconds and then release. We will ask you to repeat this test three times in total and we will record the strongest reading we get. The test takes 5 minutes and is painless.

Blood tests

During this first visit, before any other tests are done, we will take a blood sample. This will be used to check your kidney function, liver function, protein levels, check for anaemia and also measure a hormone released by the heart called b-type natriuretic peptide (NT-pro-BNP). We will take a little more blood than usual (about 50mls, two-three table spoons) which will be used for research to measure hormone levels and other markers of inflammation, clotting function and fat cell function. Before we take the blood sample, we will ask you if we can also take a small sample (around 2.5mls, half of one tea spoon) after the exercise test (see below). If you agree, to save a second needle prick, we will put into the vein a small cannula which will stay in place until after the exercise test. After the final blood test, we would pass a tiny wire up the cannula that, when withdrawn, will provide a sample of the cells lining the vein. This is something we do routinely in our work to allow us to look in detail at the cells lining the arteries and veins. Impairments of their 'teflon' function can lead to heart attacks and strokes and we want to determine why this is and whether there is something we can do about it.

The blood test with or without the cannula can leave a little bruise.

Non-invasive heart assessment

We have identified a blood pressure monitoring device called the Finapres device that is already in use in several settings in hospitals in the NHS that can describe cardiac power and the response of the arteries to a heart beat. It does this by measuring the pulse using small blood pressure cuffs around the fingers. The device uses your heart rate from an ECG and these pressure readings to create an estimation of the cardiac output (a further assessment of heart function). This test takes 5 minutes and has no side effects.

Echocardiogram (cardiac ultrasound)

You will then have an echocardiogram (ultrasound of the heart) to look at the function of the heart. It is likely that you will have had one of these before. This test is painless and takes about 30 minutes.

Optional echocardiogram for people with a pacemaker

For people with a pacemaker, we would repeat the echocardiogram with the pacemaker set to higher heart rates to allow us to assess how the heart's power changes as the heart rate increases. After this is completed, the pacemaker would be set back to its baseline values. This test has no side effects and takes around 20 minutes

Lung function test

We will assess your lung function in two ways. The first test is very common and you might recognise it from tests for asthma. We will ask you to blow through a mouthpiece as hard as you can until your lungs are empty. We will then ask you to take the biggest and strongest breath in that you can. This will assess the muscles of the chest both during breathing in and out. We will do this three times and take the best of the three readings.

The second lung test is also very straightforward. You will be asked to breathe in and out through a mouthpiece. A soft tapping noise is sent into the lungs through the mouthpiece during normal breathing and the machine then listens for the reflection. The brisker the reflection, the stiffer the lungs. This is called impulse oscillometry and takes just a few minutes. It is effortless. Neither of these lung function tests are uncomfortable or have side effects. Together they might take 10 minutes.

Exercise test

We will ask you to perform what is called a "progressive exercise test". This will usually be done on a treadmill, although sometimes we do these on a bicycle. During this test, the work rate will start very low and increase gradually every minute. The idea is that you keep going until you can do no more. The test will be stopped when you decide you can go no longer. During this test you will be asked to score your level of breathlessness at each stage during the exercise. This is an accurate way to measure your exercise capacity. During this test we will sample the air you breathe in and out through a mouthpiece to measure the concentrations of oxygen and carbon dioxide. You will also have an "electrocardiogram" or ECG (a tracing of your heart activity) measured throughout and we will attach a small plastic clip to your earlobe or a small sticker to your thigh which shines a red light and measures the amount of oxygen in your blood. You may have previously experienced one of these monitors on your finger tip on the wards or in clinic. An exercise test usually takes between 20 and 30 minutes. At the end of the test, we will take another blood sample (around 2.5mls) either through another needle puncture or through the cannula.

Optional Substudies

The following section describes additional procedures which are optional. If you decide that you do not want to have these done you can still participate in the rest of the study.

Optional Substudy 1: muscle and fat biopsies

In order to examine the effects of heart failure and diabetes on muscle and fat function, we would very much like to take a small fat (and muscle) sample from your shoulder just under your collar bone and also from the thigh. We will do this in our dedicated bed bay. This will usually take around 20-30 minutes to do but we will ask you to stay in the department for another 30-60 minutes after the sampling to make sure that the wound is clean.

The approaches will be different.

For the chest muscle sample, we will clean the skin and give local anaesthetic which can sting as it takes effect. We will then make a small cut under the collar bone. This will be around half a centimetre (5mm). Through this we can take three samples of fat (3mm x 3mm) and three samples of muscle (3mm X 3mm). Once the local anaesthetic has worked and we have made the incision, you will not notice the actual biopsies being done. The incision will be glued closed but this will leave a very small scar similar to one that can be left after chicken pox or shingles.

In order to compare the information from the pectoralis muscle with a muscle used for walking we would very much like also to take a small sample from your thigh muscle. To sample this requires an additional procedure which involves a needle biopsy of the muscle just above the knee and to the outside of the thigh. The procedure is done under local anaesthetic and takes about five minutes. The needle is a little larger than the needle used for a blood test and we will take three samples with it. The thigh muscle biopsy leaves a small puncture mark just above the knee that might ache for a day or two but will not interfere with your walking. You should consider not doing any strenuous exercise for 4-5 days after the thigh muscle biopsy.

The chest biopsy site will have a small dressing on it that can be removed after three days. The wound can be left open and the skin glue will peel off over the following two weeks.

The leg biopsy wound is dressed in several layers, including adhesive skin closure tape, a soft adhesive sterile dressing, a waterproof vapour permeable dressing and a pressure dressing comprising gauze pads and an elastic bandage. Below is some further advice on how to care for your dressing in the days following the biopsy:

How do I care for my dressing?

We advise that you follow the following regime strictly, ensuring that you keep the dressing on over the indicated time and keep the dressing dry:

- a. Remove the pressure dressing the day after your biopsy. If need be it can be removed earlier (even after 3-4 hours) but most participants are more comfortable if it is retained overnight
- b. Leave the waterproof dressing for a minimum of 24 and preferably 48 hours. This gives time for the wound to form a bacterial-proof seal.

What about bathing?

We would advise against getting the primary dressings wet as the elastic bandage is not waterproof and the gauze pads absorb water.

We advise showering after 24 hours. After two days you can bathe as normal. Should you have any questions, please telephone the ward on 0113 3927114 or the Cardiovascular Clinical Research Facility on 0113 39 28240.

The muscle, fat and blood samples will immediately be sent to laboratories in the University of Leeds where scientists will look at the structure of the muscle and fat, the function of the fat and muscle cells, the structure and function of the arteries supplying these cells and markers of heart failure, inflammation, glucose and fat metabolism, clotting studies and other tests in the blood. Unused samples will be stored at the University of Leeds for 10 years.

Optional Substudy 2: Submaximal exercise echocardiogram

We will ask some participants to allow us to study the heart's pumping function during exercise. Most heart scans are done at rest. We want to see what happens to the heart function during exercise.

The test is done on a scanning couch which has a cycle ergometer attached at the bottom end. We will ask you to pedal steadily at around half of the workload that you did during the full exercise test. During the test we will do a cardiac ultrasound and measure your blood pressure to see how the heart has adapted to the exercise. This test will usually last 20 minutes and you might feel a little tired afterwards.

Optional Substudy 3: Microneurography (muscle sympathetic nerve assessment (MSNA)) and heart rate variability

We will ask some participants to allow us to study the activity of the autonomic nervous system. This is the automatic control of heart rate and other parts of the body in response to stress or activity. In some people with heart failure or heart muscle weakness and in diabetes, increased activity of this system can have detrimental effects on heart and artery function.

The assessment is done using a technique called microneurography. This involves the insertion of very small electrode needle into a nerve under the skin below the knee. These electrodes have a tip diameter of 1-3µm, which is less than a human hair, meaning that there is no need for local anaesthetic. Some people feel a sensation of pins and needles along the nerve when the electrode is inserted, but pain is rare.

Occasionally, after the procedure, fewer than 1 in 10 people feel that their muscle is a little weak or the skin over it a little numb, but these feelings last just a few hours and never more than two weeks.

Once the needle is in, we will briefly pass a very low level current to make sure it's in the right place. To check that the needle is picking up signals well, we might ask you to squeeze a handgrip (to assess muscular strength and increase sympathetic activity) or put one hand into cold water (to test sympathetic nervous system response).

Once the recording is complete, we will remove these needles. The test takes around

In people with a pacemaker, we will adjust the heart rate through the pacemaker to see if altering the programming affects the activity of the automatic nervous system.

At the end of the visit, which we expect will last around 30-40 minutes we will invite you

to wear a heart rhythm monitor for 24 hours which you can bring or even post back to us in the following days. This will allow us to assess the natural rise and fall of your heart rate over time.

Optional Substudy 4 for those with a pacemaker: Assessment of the force frequency relationship (contractile power of the heart at higher heart rates)

We will invite people with a pacemaker to stay a little longer during the baseline visit. During this time we will do an ultrasound scan of the heart. We will then check the pacemaker and program it to temporarily increase the heart rate in stages of around 10 or 15 beats above your baseline heart rate. We will check the blood pressure and repeat the heart scan at each heart rate. It is likely that we will do this 3 or 4 times to allow us to calculate how the heart contracts at a range of heart rates. At the end of the visit, which can be combined with the baseline visit, and will take around 20 minutes, and is entirely painless, the pacemaker will be programmed back to its usual settings.

Optional Substudy 5: Cardiac MRI scan

We will invite some people to undergo an MRI scan of the heart and thigh muscles. Using an MRI scanner to assess the heart is routine and if you have had an MRI scan of your heart recently, we would be able to use that if you give us permission.

During the scan of the heart, we will occasionally ask you to hold your breath for a few moments. You will always be in contact with the team doing the scan. If you get claustrophobia or become worried during the scan, we can stop it at any time. If the team doing the scan need to look more closely at the heart muscle or its function, they may give you some dye into one of the veins and an injection of a drug that makes your heart beat harder and faster. Overall the heart scan takes around 20-30 minutes.

Once the heart scan is finished, whilst you are in the scanner, we would also like to measure the volume of your thigh muscles. This will add 5 minutes to the scan length.

Optional Substudy 6: Continuous ambulatory blood glucose measurement.

We would like to assess how your blood sugar varies over two weeks. This could help identify people with heart failure who might be at greater risk for future problems. To do this we will use a sensor called the Libre Freestyle that sticks to the back of your upper arm. This sensor measures the blood glucose continuously for two weeks and can store these data. It can also send the information to your mobile phone or to a reader that we could loan you.

The sensor take just a few minutes to put on your arm, and does not stop you showering or bathing. It does not usually cause any side effects although rarely can cause a local skin reaction. This settles once the sensor is removed.

We will show you how to take the sensor off and it can then be posted to us or you can bring it back if you are attending for another optional substudy.

Genetic analysis

We will not be using the blood test to search for specific genes that code for specific conditions. It is therefore highly unlikely that we will identify a genetic condition that you didn't know you had. Our gene analysis looks for patterns within the codes that might be linked with the presence of diabetes or modified by diabetes and also how these genes affect the body's metabolism.

Telephone check

We will telephone you after one week to check that everything is fine.

Long term check

We will check the NHS system every year for up to 10 years after you finish this study to see how you are doing.

Data storage

The data we collect as part of the study will be stored for five years *after the end of the study*. This means that your data could be stored for up to 10 years. This is routine and ensures that the safety of the study can be audited. The identifiable data (the data that are connected to your name and details) will all be stored on the Leeds Teaching Hospitals electronic patient record system. Only data that have been anonymised (your personal identifiable details have been removed) will be shared securely with colleagues at the University of Leeds.

Risks

The risk of any adverse event with this project is very small. You will be able to stop each of the tests if you develop shortness of breath or angina. The risk of an exercise test is very small, and the heart ultrasound scan is without risk.

None of the questionnaires ask any sensitive or embarrassing questions.

Exercise testing can leave you feeling a little tired following the test, but you should rest for the remainder of the day. Exercise tests are safe in patients with heart problems.

The biopsies will each leave a little scar which will be less than 5mm across on the chest and a pin point on the thigh but we do not expect any other complications from this.

As described, if you have a pacemaker, we may reprogram this to get more information during the baseline visit. This can make the heart go faster, and in some people can rarely lead to angina in which case we will stop the test. At the end of the testing period, we will reset the pacemaker to the original programming.

The risks of the microneurography test are described above. Some people feel a little tingling and numbness over the puncture site for a few weeks, but this is very rare.

Some people with claustrophobia do not like having an MRI scan but it's often difficult to predict who will and who will not tolerate the scan. We are always happy to stop the scan for people who find it distressing. We will use a special dye injected into the veins to look at the heart and its blood supply a little better. This is extremely safe but occasionally people have an allergic reaction which is noticed as a rash within a few minutes. The rash resolves quickly with anti-inflammatory injections and the MRI unit is experienced in the management of this. To look at the blood supply in more detail we may also use an agent that increases the blood flow through the heart. This can cause a flushing feeling and a sensation of anxiety. These symptoms resolve fully within a few seconds.

The continuous blood sugar measurement is also increasingly routine for people with diabetes mellitus and the team are very experienced at applying the patch that does the measurement. The most frequent side effects are skin irritation due to the patch used to take the readings. These settle very quickly once the patch is removed.

Benefits

It is possible that collecting all of this information about you and your heart will benefit you by allowing us to adjust the treatments you receive. Having an exercise test can also give people the confidence to do more exercise in their daily lives. However, for most people, the tests will not lead to an alteration of their treatment or benefit them directly.

If we find anything unexpected or abnormal during these tests we will inform your GP and help plan further investigation or treatment either with your GP or the relevant speciality in the hospital.

Participation

Your participation in this study is voluntary. You can choose not to participate or you may withdraw at any time without affecting your medical care. There will be compensation for reasonable for travel expenses such as taxi, bus and train tickets if you bring the receipts with you to the visits. With your permission we inform your GP that you are participating in this study.

Long term follow-up

We would like to keep your details on a secure database within Leeds Teaching Hospitals NHS Trust for up to 5 years after the end of the study (so for up to ten years inf the study takes us 5 years to complete). This will allow us to find out how you are doing from the Leeds Teaching Hospitals NHS system.

At the end of the study we will write to you to describe the results.

Compensation

If you become ill or are physically injured as a result of participation in this study, medical treatment will be provided. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities.

Part 2

What if relevant new information becomes available?

We are unlikely to be in a situation where a new treatment is uncovered, but if that were to happen we will get in touch with you or your general practitioner. If the study is stopped for any reason, we will tell you.

What if I don't want to carry on with the study?

If you wish to be withdrawn from the study for whatever reason, we are happy to organize regular follow-up as usual. You can withdraw from the study at any time. We would like to use information collected while you were taking part.

What if I lose capacity to make my own decisions?

If you lose capacity to make your own decisions during the study collection period, we would not do any further tests. On the other hand, once we have completed the initial testing, it will not be practical for us to check on this sort of detail, and since the later stages of the study do not require any involvement we will not withdraw you from follow-up unless you specifically tell us that you do not want us to check up on you through your record on the NHS system.

What will happen to my blood and tissue samples?

These will be stored carefully and disconnected from your personal details according to the Human Tissue Authority guidelines at the University of Leeds. If you ask us specifically to destroy them, we will do so.

We will keep these samples long term (up to 10 years) and do further tests on them when these become available. It will not be practical for us to contact and ask all the participants in this study whether we can use their samples for a particular or new test. In this case, we would therefore not contact you (or your family) except in the highly unlikely case that we found something critical. Colleagues at the University of Leeds will not have access to your personal details. The samples will be coded so the doctors running the study (Dr Witte and his team) can link the samples back to your clinical data if necessary.

It is possible that Dr Witte and the research team are approached by, or develop collaborations with, other research groups across the world. These groups could include other universities or commercial companies. In response to an ethically approved and scientifically sound proposal by these groups, Dr Witte or the research team could agree to share the samples and clinical information for research purposes. This clinical information will not however include details that allow anyone to identify you.

Complaints

If you have a concern about any aspect of this study, you should ask to speak to Dr Klaus Witte who will do his best to answer your questions (0113 3926642 or 00447768254073). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital. For independent complaints you can also contact the University of Leeds Sponsor Representative on governance-ethics@leeds.ac.uk.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Leeds University or Leeds Teaching Hospitals NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Confidentiality

For follow-up purposes, we will need to collect and securely store your full name, NHS number and date of birth until 10 years after your visit in our secure database. All the information obtained during the study will be held in the strictest confidence and within the regulations given with the Data Protection Act 2018. No names or identifying information will be used in any publication or presentations. The only people with access to your details will be the people carrying out the study. No data about you will be transferred in any way that allows people not associated with the study to know who you are. The reason for doing this is so that in future we can look back and see how the information we obtained and the results of the study relate to things that happened to you subsequently.

During the regular monitoring of this study your medical records may be looked at to ensure that the information that is collected is accurate.

What will happen to the results of the study?

The results of the overall study might not be known for several years so if you are

interested in receiving the details of the entire study please let the study team know. The results of the study will be published in international peer-reviewed journals.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by the XXXXXX

Who is funding this study?

The study is being funded by the British Heart Foundation through a grant to the University of Leeds.

Questions

If you have any further questions about the study, or would like to be included in this research, please call Dr Klaus K Witte on 0113 3926642 or write to Dr Witte at the Cardiology Department, G-floor, Jubilee Wing, Leeds General Infirmary, Great George Street, Leeds, LS1 3EX.

GDPR

How we will use the information about you?

We will need to use information from you and your medical records for this research project.

This information will include your name, NHS number, date of birth and contact details. People will use this information to do the research or to check the 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 and your samples will be identified by a code number that will be stored on the Leeds Teaching Hospitals NHS Trust system.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so that 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.

Anonymised information

The Leeds Teaching Hospitals NHS Trust will not pass identifiable information to the University of Leeds. All data going to the University of Leeds will be de-identified. The only people in the University of Leeds who will have access to information that identifies you will be people who need to contact you to (for example Dr Witte's research team) or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government.

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.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from the hospital and NHS records systems. If you do not want this to happen, tell us and we will stop.

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 that we hold about you.

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

The University of Leeds is the sponsor for this study. Researchers from the University of Leeds 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 the University of Leeds is responsible that your information is looked after and used properly. The Leeds Teaching Hospitals NHS Trust will keep identifiable information about you on behalf of the University of Leeds for 5 years after the study has finished.

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
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by sending an email to governance-ethics@leeds.ac.uk
- by calling the Clinical Research Facility on 0113 392 8240
- by contacting the University of Leeds Data Protection Officer on DPO@leeds.ac.uk and also at <https://dataprotection.leeds.ac.uk/wp-content/uploads/sites/48/2019/02/Research-Privacy-Notice.pdf>
- by contacting the Patient Advice and Liaison Service at Leeds Teaching Hospitals NHS Trust on 0113 206 6261 or via email at patientexperience.leedsth@nhs.net