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TIPAL:
Treating people with Idiopathic Pulmonary fibrosis with the Addition of Lansoprazole

Participant Information Sheet

Thank you for your interest in our study

1. Introduction: Why are we doing this study?

Idiopathic Pulmonary Fibrosis is a disease which results in damage to the lung tissue. It is characterised by progressive loss of lung function (measured by breathing tests) and increasing breathlessness. It is incurable and there are few available treatments. It is thought to occur because of tiny "scars" (which we call fibrosis) that develop throughout the lungs.

These breathing tests include spirometry assessments, which measure the amount of air you can breathe out and how fast you can blow it out. Spirometry tests can be carried out at hospital, GP surgeries or your home provided you have the correct equipment and appropriate training. These tests are completed regularly to monitor lung function.

Previous research suggests idiopathic pulmonary fibrosis progresses slower if patients regularly take anti-acid drugs (like lansoprazole) and they may be likely to survive longer. Such drugs reduce acid which is thought to cause the scar formation and/or may directly reduce the amount of scar tissue. This is why people are often prescribed these drugs, but we don't really know if they benefit patients; the aim of our study is to find this out.

Why have I been invited?

We plan to recruit 298 participants with idiopathic pulmonary fibrosis across the UK. We want to know whether lansoprazole, when given alongside current treatments, slows down the decline in lung function associated with idiopathic pulmonary fibrosis.

Do I have to take part?

No. The decision to participate is entirely up to you. If you are interested in taking part, we will ask you to sign a consent form. If you do decide to take part, you are free to withdraw at any time, without giving reason and without affecting the standard of care you receive. If you are not interested in taking part, it will not influence your future treatment in any way. We encourage you to discuss whether to participate with your family, friends and GP.

2. What will happen to me if I take part?

To find out if lansoprazole benefits people with idiopathic pulmonary fibrosis, we need to compare a group of people with idiopathic pulmonary fibrosis who will be given lansoprazole with a similar group of people who will be given a placebo. A placebo is a "dummy" treatment which looks like the genuine medicine but does not contain any active ingredient(s).

To try to keep the groups as similar as possible, the group you will be allocated will be selected randomly, in a process similar to tossing a coin. You will have an equal chance of getting the lansoprazole treatment or the placebo.

Neither you nor your doctor will know whether you are receiving the lansoprazole or the placebo; this is called a double-blind study. However, if your doctor needs to find out which group you are in for emergency or safety purposes, they can do so.

If you are interested in taking part, we will make plans to see you at your next clinic appointment or speak to you via phone/video call.

Before agreeing to take part, you should check any private medical insurance you have will not be affected by your participation.

This study is designed so that you can participate without visiting the hospital at all or you can visit the hospital if you and your research team prefer.

Pre-entry to the study:

If you decide to participate, a member of the research team will ask you to sign a consent form either on paper or electronically via an email link to confirm you are willing to take part.

Entry into the study:

You will then be asked to:

- List the medicines you take and any other health problems you may have.
- Complete 9 questionnaires. These will take about 30 minutes to complete in total. They aim to find out how you feel about your condition, and any cough and breathlessness you may have.
- Confirm you are happy to receive a study supplies kit, containing a home spirometer with disposable mouthpieces and study tablet, to allow you to complete breathing tests at home during the study. The tablet will have an app pre-installed which links to the spirometer via Bluetooth to transfer your breathing test data from the spirometer to the research teams at the hospital and Norwich Clinical Trials Unit. We will provide a sim card, with a sufficient data allowance for the study.
- Attend a video training call with a member of the research team to learn how to use the spirometer and tablet and perform the breathing tests.
- Complete daily breathing tests at home, following the instructions and using the equipment provided, for up to 14 days, to achieve 5 days of good quality data. The breathing tests will be completed only once weekly after you receive your study medication.
- Allow us to take a blood sample of 10mls (2 teaspoons) to make sure it is safe for you to take part by testing that your kidneys and liver are working normally. Any surplus blood will be destroyed. The samples will be kept securely. This will either be taken at your GP surgery or hospital.
- If you are attending the hospital, and provided you are willing, we may ask to take an additional blood sample for research purposes which will be analysed in future ethically approved studies. 20mls (4 teaspoons) will be taken to analyse the biomarkers in your blood which will provide information about idiopathic pulmonary fibrosis. Finally, a further 10mls (2 teaspoons) may be taken for genetic analysis if you consent to this part of the study (see section 8); this sample may be taken at another timepoint if the first visit takes place outside the hospital. The samples will be identified by a unique code and will not have your name or other details written on them. They will be kept securely.
- *Optional*: You also will be asked if you would like to subscribe to receive study updates via email and how you would prefer to complete the questionnaires (on paper or electronically via an email link).

Optional additional tests

Cough and activity sub-study

If you are eligible and willing to do so, we will ask you to wear a cough monitor for 24 hours. This is so we can find out how many times people with idiopathic pulmonary fibrosis cough in a day. A cough monitor is a sound recorder so it will record activities around you whilst you are wearing it. We use software to cut down the recording to where there is no coughing, but sometimes we may need to listen to the whole 24 hour recording including speech. Further details are given in section 8.

We may ask if you are willing to wear a wrist-based activity monitor during this time period as well. The activity monitor will help us tell whether coughing affects your activity and/or sleep or vice versa.

Choosing not to participate in this part of the study will not have any impact on your trial participation or care. If you decide to take part in the sub-study, the equipment will be sent to you and collected from you at home by a courier, arranged by a member of the Norwich Clinical Trials Unit team (packaging will be provided). A member of the research team will contact you via video call to help you fit the cough and activity monitors and start the recordings.

Chest Scans

If you are willing to do so, you will be invited to have a chest/lung computed tomography (CT) scan within 3 months of starting the study. You will have had one of these scans as part of your diagnosis or routine clinical care. Indeed, if you have had one or planning to have one within 3 months of starting the study, we will not ask you to have another. To have the CT scan done you will have to lie flat on a bench which moves inside a large, short tunnel (like a polo mint). It takes about 5 minutes to do. You will have to come to the hospital for this. We expect you will need to be on site for no more than one hour depending on the usual NHS clinic uncertainties and waiting times on the day beyond the control of the research team(s).

Entry to the study continued: You will then be randomly allocated to either receive the active drug or the dummy drug. Which you will need to take as directed (see section 6 below). You will also be given you a card to carry with you explaining you are taking part in the study, which you should show any doctors, nurses etc. you see during the study.

Table showing study measurement times

		Measurement Time				
Procedure / Assessment	*Pre-entry to the study*	*Entry to the study*	*3 months*	*6 months*	*9 months*	*12 months*
Informed consent taken	X					
Entry criteria checked	X					
Study supplies kit sent to you	X					
Demographic information, medical history and patient characteristics collected		X				
Chest CT scan (if applicable) or images collected from medical notes (where available)		X				X
Trial medication allocated		X				
Trial medication dispensed		X		X		
Safety blood tests (only as required at 3/6/9 months)		X	X	X	X	X
Research biomarker blood tests		X				X
Blood sample taken **once** at a face-to-face visit at any measurement time, for genetic analysis if agreed		X	X	X	X	X

Questionnaires completed by you		X	X	X	X	X
Weekly breathing tests completed at home		←	Weekly throughout study			→
Cough and activity monitoring if applicable/agreed		X	X			
Side-effects checked			X	X	X	X

Study measurement times:

We would like to see/speak to you again after 3 months, 6 months, 9 months and 12 months. At all of the study measurement times we will ask you to:

- Tell us if there are any changes in the medicines you are taking and about any side-effects or problems you may have had since your last visit/call.
- Continue to carry out **weekly** breathing tests at home throughout the study. You should complete breathing tests daily for up to 14 days, to achieve 5 days of good quality data in your final week on the study medication.
- Fill in 7 questionnaires at the 3 month measurement time, 5 questionnaires the 6 and 9 month measurement times and 10 questionnaires at the 12 month measurement time which will take about 20-35 minutes to complete.

If you do not attend the hospital at the study measurement times, a member of the hospital research team will contact you via phone/video call to collect the information as above.

If we do not receive your completed questionnaires or receive the results of your blood tests within the expected timeframe, a member of the research team will contact you.

At 3/6/9 months only:

We may need to take a blood sample of 10mls (equivalent to 2 teaspoons) to make sure the study medication is not causing a problem with your kidneys or liver, only if your doctor thinks they are required. This will either be taken at your GP surgery or at the hospital and will be sent to your hospital laboratory. Any surplus blood will be destroyed.

At 3 months only if you have agreed to take part in the cough and activity sub-study:

If you agreed to wear the cough monitor at the first measurement time we will ask you to wear it again for another 24 hour period at 3 months only. You may also be asked to wear an activity monitor as well. A member of the Norwich Clinical Trials Unit research team will carry out video call to help you fit the monitor(s) and start the recording(s), and arrange couriers to deliver/collect the monitors to you at home as before.

12 months only:

If you attend the hospital in person at the 12 month measurement time, we may also take 20mls of blood to analyse the biomarkers in future ethically approved studies (a total of up to 30mls of blood will be taken at this visit), if you consent for us to do so as explained above.

You will have a short refresher video call (no longer than 15 minutes) with a member of the research team before you start your daily breathing tests to make sure we collect good quality data to compare against that from the start of the study. Once you have completed these daily blows, a member of the Norwich Clinical Trials Unit team will contact you to arrange a courier to collect the spirometer and tablet. Packaging will be provided if needed.

Optional additional questionnaire/test:

Feedback questionnaire:

We will ask you to complete an optional participant feedback questionnaire on your study experience as this is one of the first studies which can be done at home. You can choose whether to complete this on paper or electronically. If you choose to do it on paper, we will provide a freepost envelope to return it in. You will be posted/emailed a £5 shopping voucher to thank you for your time to complete this questionnaire.

Chest scan sub-study only if you agreed to this at the start:

We will invite you to attend for a chest CT scan no more than 3 months before or after you finish the study, as described above. If you have had one or one is planned for your routine care within 3 months of finishing the study, we will not ask you to have another.

3. What is Lansoprazole?

Lansoprazole is a type of anti-acid treatment called a Proton Pump Inhibitor and is commonly used to treat conditions involving excessive stomach acid and to prevent stomach and intestinal ulcers. It has been used throughout the world for approximately 25 years.

Many patients are prescribed proton pump inhibitors like lansoprazole as anti-acid treatments without any clear benefit. If you already receive this treatment, and wish to be enrolled in the study, you will be offered the opportunity to complete a two week withdrawal period if you agree and your consultant thinks it is safe to do so. During this time, you will no longer take proton pump inhibitor and we will closely monitor you to check if your heartburn/reflux symptoms return. If they do not return after the two week period, you will be able to enter the study. You are still permitted to take over the counter anti-acid treatment such as Rennies, Gaviscon etc. throughout the study.

We will arrange for the study medicine to be delivered to you at home. You will need to keep the study medication at room temperature (under 25°C). You will be asked to take 2 capsules (2 x 15mg lansoprazole or placebo) of the study medication twice per day, every day for 12 months, 30 minutes before food.

If you experience side effects, we ask that you contact your doctor to discuss it. There may be an opportunity for you to reduce the study medication dose to 1 capsule (15mg of lansoprazole or placebo) twice per day, at least 30 minutes before food, which may help stop the problems you are having. You are also able to reduce the dose and/or stop taking the study medication if you wish or clinician advises to for any other reason.

What are the alternatives to treatment?

The study medication is not an alternative to any approved treatment that you may require, it is being provided in addition to your usual medication.

What treatments should I avoid?

There are a number of treatments you should not take while you are in the study including: atazanavir, ketoconazole, itraconazole, tacrolimus, fluvoxamine and/or methotrexate. Your doctor will review the medicines you are taking before and during your study involvement. Participants taking warfarin, digoxin and/or theophylline may have extra monitoring through blood tests during the trial as an extra safety precaution.

You must not carry out the breathing tests if you have any of the following: coughing up blood; punctured lung; unstable cardiovascular status or recent heart attack or pulmonary embolus; dilated abdominal or brain blood vessels; recent eye, chest or abdominal surgery; or any other acute illness or symptom which might interfere with test.

4. What are the potential side effects?

As with all drugs, lansoprazole can sometimes cause unwanted side effects in some people. For lansoprazole, the following have been reported:

Common (affects between 1 in 10 and 1 in 100 people)**:** headache, dizziness, vomiting, nausea, diarrhoea, stomach-ache, constipation, flatulence, dry mouth or throat, fundic gland polyps (benign), increase in liver enzyme levels, urticaria, itching, rash, fatigue.

Uncommon (affects between 1 in 100 and 1 in 1000 people)**:** leucopenia, thrombocytopenia, eosinophilia, depression, fracture of the hip, wrist or spine, arthralgia, myalgia, oedema.

Rare (affects between 1 in 1000 and 1 in 10,000 people)**:** anaemia, hallucination, insomnia, confusion, paresthesia, vertigo, restlessness, somnolence, tremor, visual disturbances, pancreatitis, candidiasis of the oesophagus, glossitis, taste disturbances, hepatitis, jaundice, petechiae, purpura, erythema multiforme, photosensitivity, hair loss, interstitial nephritis, gynaecomastia, angioedema, fever, hyperhidrosis, anorexia, impotence.

Very rare (affects 1 in 10,000 people)**:** pancytopenia, agranulocytosis, anaphylactic shock, colitis, stomatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, increased cholesterol and triglyceride levels, hyponatremia.

Not known (frequency cannot be estimated from available data)**:** hypomagnesaemia, hypocalcaemia, hypokalaemia, visual hallucinations, subacute cutaneous lupus erythematosus.

The doctor and local study team at your hospital are available for you to call if you experience any unwanted side effects. In an emergency you should contact your hospital or GP.

Some reports suggest that drugs like lansoprazole increase the risk of chest infections including pneumonia and your doctor and local study team will be monitoring this closely.

Lansoprazole may increase osteoporosis. If you are already at risk of developing this, please discuss this with the local study team so your doctors can assess if it is safe for you to take part and/or whether you need to take other medications to prevent osteoporosis.

What if I forget to take the tablets?

If you forget to take a dose, take the next dose at the right time. Do not take a double dose to make up for a forgotten dose.

What are the possible disadvantages of taking part?

You may not get the active treatment (lansoprazole) and may receive the dummy treatment, but you will still receive any approved treatment for idiopathic pulmonary fibrosis.

It may be necessary for you to travel to the hospital for visits in addition to your routine clinic visit(s). If you are required to make an additional visit(s), we will reimburse your travel expenses up to a total of £100 per participant.

If you take part in the chest scan sub-study you will be reimbursed £14.50 per CT scan (to cover time and parking) and 45p per mile travel expenses (for up to 50 miles), for each visit.

The blood tests may cause discomfort and bruising. The questionnaires will take time to complete. The breathing tests may cause slight breathlessness, difficulty breathing or chest discomfort for a few minutes. You may experience the side effects mentioned above.

If you take part in the chest scan sub-study you will have up to two chest CT scans. All of these will be extra to those that you would have if you did not take part. Although as explained above, if you are due to have these scans anyway, you will not have any extra scans performed. These procedures use ionising radiation to form images of your body. Ionising radiation may cause cancer many years or decades after the exposure. In patients with your current clinical condition, the chance of this happening to you is extremely small.

You are free to withdraw at any time and without giving a reason and this will not affect the standard of care you receive. You can stop the study medication but keep in contact with us to let us know your progress. Information collected will still be used. If you withdraw from the study, data and samples collected up to the point of your withdrawal will still be used unless you state otherwise.

What are the possible benefits of taking part?

It cannot be guaranteed that the study will help you but the information that we get will improve our ability to treat patients with idiopathic pulmonary fibrosis in the future.

You will be able to monitor and track your breathing tests during the study.

If you take part in the chest scan sub-study, your doctor will have access to the scans and they may find this useful to understand your condition.

What happens at the end of the study?

Lansoprazole is not currently used to treat patients with idiopathic pulmonary fibrosis, and you will stop taking the study medication after 12 months. However, if we find out that you have been taking lansoprazole and that you have had a noticeable benefit from it, we will be able to tell your doctor and they may decide to prescribe this or something similar.

The study results will be published in scientific journals and presented at scientific meetings. You will not be named or identified in any way. If you would like information about the results, please contact the Principal Investigator named below.

What if new information becomes available during the study?

Sometimes we get new information about the study medication. If this happens, your local study doctor/team will tell you the new information and discuss what this means. If, once you have had time to think about what you have been told, you decide not to carry on in the study, your routine care will

continue as normal. If you decide to continue in the study you may be asked to sign an updated consent form.

What if there is a problem?

If you are concerned about any aspect of this study you should speak to your doctor who will answer your questions. If you wish to make a complaint, you can do this through the NHS Complaints mechanisms. Contact details can be obtained from [local Patient Advice and Liaison Service (PALS)].

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed during the research due to someone's negligence, you may have grounds for legal action for compensation against your hospital, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you. If something goes wrong during the study, you will be covered by the NHS insurance standard policy.

5. Will my taking part be kept confidential?

Yes. All information which is collected about you during the research will be held securely in accordance with the Data Protection Act and the General Data Protection Regulation. It will be kept for 25 years after which it will be disposed of securely. All of your study data will be labelled by a code and will not have your name or any other details about you on it. We refer to this as linked anonymised as although your sample is anonymous it can be linked to you by a code. The code will only be able to be linked to your trial data by your hospital doctors and nurses. It will be kept securely.

Participants will have a profile created on the home spirometry app for them. This profile will contain clinically relevant data required to assess and grade the breathing test data based on international guidelines (as would be done with tests carried out at the hospital). Your profile will be identified by your study code. The breathing test data will be transferred from the app on the tablet provided to the research team. Spirometry app terms and conditions can be found at: https://norwichctu.uea.ac.uk/tipal/

Some trial data will be collected by the Norwich Clinical Trials Unit team through the British Thoracic Society (BTS) Idiopathic Pulmonary Fibrosis and Sarcoidosis Registry, a national registry that collects data routinely from NHS trusts. We will use this registry data at Norwich Clinical Trials Unit to see whether lansoprazole was beneficial for you in the long-term (up to life-long). You will be asked to sign an additional form to confirm you are happy for your data to be stored on the registry. The BTS will ensure data is held in compliance with legal and data protection requirements.

The recordings from the cough monitor will be transferred to our collaborators at Manchester University NHS Foundation Trust by Vitalograph via a secure web-based database. Recordings will be anonymised; they will be labelled with your study code only. Manchester University NHS Foundation Trust and Vitalograph will ensure data is held in compliance with legal and data protection requirements.

Norwich Clinical Trials Unit is part of the University of East Anglia, who with the Sponsor, Norfolk and Norwich University Hospitals (NNUH) NHS Foundation Trust, will act as joint Data Controllers for this study.

The University of East Anglia (UEA) also acts, with the BTS, spirometer providers, Manchester University NHS Foundation Trust, Vitalograph and Brainomix, as Data Processors for this study. The lawful basis for processing personal data collected in this study is that it is a task in the public interest. You can find out more about how we use your information at https://norwichctu.uea.ac.uk/personal-data or

contacting the Data Protection Officers (dataprotection@uea.ac.uk or 01603 592431 at UEA, or info.gov@nnuh.nhs.uk or 01603 286286 at NNUH).

Other third-party researchers and commercial companies may wish to access anonymised data from this study in the future (anonymised data does not include names, addresses or dates of birth, and it is not possible to identify individual participants from anonymised data). If this is the case, the Chief Investigator will ensure that those receiving your data comply with legal, data protection and ethical guidelines.

If you join the study, the data collected for it, together with any relevant medical records, may be looked at by authorised persons from UEA, the Research and Development Department of your local hospital and the Regulatory Authorities to check that the study is being carried out correctly. They all will have a duty of confidentiality to you as a research participant.

With your permission, your GP will be informed of your participation in this study.

How will we use information about you?

We will need to use information from you, from your medical records and some we collect during the study for this research project. This information will include your:

- Initials – to be shared with the Norwich Clinical Trials Unit team only
- Name, date of birth and contact details – your name, address and phone number will be shared with the Norwich Clinical Trials Unit team, study drug manufacturers and courier(s) to arrange delivery of study medication and equipment. These contact details will also be shared with a courier to facilitate shipping the spirometry kit and the cough/activity monitors (if applicable). Your date of birth will be collected only as an identifier on the trial medication prescription to ensure it is prescribed to the correct person and will be shared with Norwich Clinical Trials Unit and trial drug manufacturers only. The Norwich Clinical Trials Unit team will also receive a copy of your signed consent form.
- Email address – will be shared with the Norwich Clinical Trials Unit team only if you wish to consent to participate electronically, receive study updates, opt to complete questionnaires electronically and to receive your shopping voucher for the feedback questionnaire if you choose to complete it (NB the voucher may be posted to you if you prefer).

People will use the study information to do the research or to check your records to make sure that the research is being done properly. 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. If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital and the BTS IPF registry. 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 we collect.

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/

- www.hra.nhs.uk/patientdataandresearch
- By contacting the Data Protection Officer(s) (see contact details in section 5)
- By asking one of the local research team (see contact details in section 7)
- By contacting the co-ordinating team (see contact details in section 7)

6. Further information

Who is organising and funding the research?

This study is being organised by the Norfolk and Norwich University Hospital NHS Foundation Trust.

The research is being funded by the National Institute for Health Research (NIHR), Health Technology Assessment (HTA) NIHR reference number: 127479. Brainomix, a company who specialises in using computers to report CT scans, is providing the costs of undertaking the chest scan sub-study.

Who has reviewed the study?

All research in the NHS is reviewed by an independent Research Ethics Committee to protect the safety, rights, wellbeing, and dignity of participants. This study has been reviewed and approved by the East of England – Cambridgeshire and Hertfordshire Research Ethics Committee.

In addition, the study has also been reviewed and approved by the Medicines and Healthcare Products Regulatory Agency (MHRA) who are responsible for regulating clinical trials involving drugs in the UK. The NHS Health Research Authority and the Research and Development Department of your local hospital have also reviewed and approved the study.

7. How to contact us

If you have any questions or would like more information, please contact either your local researchers or the co-ordinating team (details below).

Local Researchers Details:

Local PI Name,
Local PI Address
Local PI Phone
Local PI Email

Co-ordinating Team Details:

Professor Andrew Wilson
TIPAL
Norwich Clinical Trials Unit,
University of East Anglia
Norwich,
NR4 7TJ
tipal@uea.ac.uk

Thank you for taking the time to read this information leaflet.

8. Further information

The genetic sample

As part of the study, you will be invited to provide a blood sample for genetic analysis. By looking at DNA (genes – the building blocks of life) in your blood, researchers may be better able to understand how patients differ in the way they respond to lansoprazole. Approximately 10mls (2 teaspoons) of blood will be taken once at any study measurement time attended at the hospital. Your sample will be labelled by your study code. Samples will be shipped to Norwich Research Park Biorepository for analysis in future research. These analyses will not provide a diagnosis for you or be used to prove any disease-causing genes which may carry any risk of disease for you or your close relatives.

Participation in the genetic research is voluntary. If you decide to take part, you are still free to withdraw at any time. If you change your mind and you do not have to give a reason why, and your sample will be destroyed if you wish. There will be no change to your medical treatment or to your participation whether or not you provide this sample. If you withdraw from the genetic analysis, the researchers will only keep any study information collected up to that point.

The cough and activity monitors

If you take part in the cough sub-study, a researcher will supervise you attach a sticky pad to your collarbone and attach a small microphone to your clothing by video call. This will make sure the monitor is fitted correctly and provides an opportunity for you to ask questions. The cough monitor itself will be kept in a 'bumbag' around your waist.

Although the monitor is designed to record the number of times you cough, it will also record activities going on around you whilst you are wearing it. This includes speech, therefore the research team at Manchester University NHS Foundation Trust and Vitalograph will have access to any personal information disclosed and recorded during the monitoring period. The analysis team will use a software algorithm which cuts down the parts of the recording where there is no coughing e.g. speech, sounds when you are sleeping or distant noises like the television. These cut down recordings will be listened to by a trained researcher at Manchester University NHS Foundation Trust who will count the number of times you cough over the 24 hours. Please be aware that if the researchers hear something on the recordings which may place either yourself or others in danger, they are required to follow standard reporting procedures.

The activity monitor will also record your sleeping patterns (e.g. time spent in each stage of sleep, temperature changes whilst you sleep etc.). We will use this to investigate if there is a relationship between idiopathic pulmonary fibrosis, cough, sleep, and reflux symptoms.

The monitors must be worn for 24 hours and you must not get them wet. Once the monitors are fitted, you will be able continue your daily activities. They will turn off automatically.

The chest scan sub-study

This sub-study is to help us gain more information on how the lungs respond to the study medication by using new sophisticated software to analyse the scans. The images will show us whether lansoprazole improves the scarring on the lungs. We will also be able to study the images alongside the breathing test data, which may help provide further information on idiopathic pulmonary fibrosis.