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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 patient’s lung function.

Previous research suggests that 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 from different regions of the UK. We want to know whether lansoprazole, when given alongside current treatments, slows down the decline in lung function which is 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 in the study, we will ask you to sign a consent form either on paper or electronically. 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 contains no active ingredient(s).

To try to ensure the groups are 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, he/she 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 in this study 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 contact you by phone/video call/at the hospital to ask you to:

- Sign a consent form either on paper or electronically via an email link confirming you are willing to take part in the study. If sign the consent form electronically, you will need to verbally consent to sharing your email address with the research team to facilitate this.
- Confirm you are happy to receive a study supplies kit containing a home spirometer with disposable mouthpieces and a smartphone or tablet to allow you to complete breathing tests at home throughout your participation in the study. The smartphone or 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 study purposes only.

Entry to the study:

Provided you are able to complete the spirometry assessments correctly, you will be asked to:

- List the medicines you take and any other health problems you may have if this information is not in your medical notes.
- Complete 9 questionnaires. These tick-box questionnaires will take about 30 minutes to complete in total. They aim to find out how you feel about your condition and about any cough and breathlessness you may have.
- Attend a video training call with a member of the research team to learn how to use the study spirometer. Carry out daily breathing tests at home following the instructions and using the equipment provided for up to the next 14 days, to achieve 5 days of good quality data.
- Allow us to take a blood sample. 10mls (2 teaspoons) of blood are taken routinely to make sure it is safe for you to take part in the trial by testing that your kidneys and liver are working normally. Any surplus blood from these safety tests will be destroyed. The samples will be kept securely. This will either be taken at your GP surgery or at the hospital if you are attending in person.
- If you are attending the hospital, and provided you are willing, we may also 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). Therefore, we may take a total of up to 40mls (8 teaspoons) of blood at the study measurement time if you attend the hospital in person. 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.

If you are eligible and willing to do so, we will also ask you to wear a cough monitoring device for 24 hours. This is so we can find out how many times people with idiopathic pulmonary fibrosis cough in a day. A cough monitoring device is a sound recorder so it will record activities around you whilst you are wearing it. We use software to cut down the recording where there is no coughing but sometimes we may need to listen to the whole 24 hour recording including speech. Further details of the sub-study are given in section 8. We may ask if you are willing to wear a wrist-based activity monitoring device 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 monitoring devices will be sent to you and collected from you at home by a courier, arranged by a member of the Norwich Clinical Trials Unit trial team (packaging will be provided). A member of the research team will contact you via video call to help you fit the devices and start the recordings.

Table showing study measurement times

Procedure / Assessment	Measurement Time					
	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				
Routine chest CT scan images collected from medical notes (where available)		X				X
Treatment allocated		X				
Trial Drug dispensed		X		X		
Safety blood tests*		X	X	X	X	X
Research biomarker blood tests taken for analysis in future ethically approved studies		X				X
Blood sample taken once at a face-to-face visit at any measurement time, for genetic analysis if consented to do so		X	X	X	X	X
Questionnaires completed by you		X	X	X	X	X
Weekly breathing tests completed at home		← Weekly throughout study participation →				
Cough count (and activity if applicable) monitoring		X	X			
Side-effects checked			X	X	X	X

*safety blood tests will only been conducted at the 3/6/9 month study measurement times if your doctor think they are required.

We also invite you to allow us to undertake a genetic analysis on a 10mls blood sample if you consent to this part of the study (see section 8). This sample will be taken **once** only at any study measurement time where you attend the hospital in person.

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 study questionnaires (on paper or electronically via an email link).

You will then be randomly allocated to either receive the active drug or the dummy (placebo) drug. Whichever you are given, you will need to take it as directed – every morning and at night (12 hours apart), at least 30 minutes before food, (see section 6 below). We will arrange for the medicine to be delivered to you at home.

You will be asked to carry out **weekly** spirometry tests, at home with the kit provided, once you start taking the study medication. A member of the research team at your hospital will contact you if you forget to upload breathing test data.

You must not carry out the breathing tests if you have any of the following: haemoptysis; pneumothorax; unstable cardiovascular status or recent myocardial infarction or pulmonary embolus; thoracic, abdominal or cerebral aneurysms; recent eye surgery e.g. cataract; presence of an acute illness or symptom that might interfere with test performance (e.g. nausea, vomiting); recent thoracic or abdominal surgery.

Study measurement times:

We would like to see/speak to you again after 3 months, 6 months, 9 months and 12 months. This can be done without you having to attend the hospital or if you are attending in person for your regular clinic visit, the research team may catch up with you then if possible and you are willing.

At all of the study measurement times (3 months, 6 months, 9 months, 12 months) 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.
- Allow us to take a blood sample of 10mls (equivalent to 2 teaspoons) to make sure the trial treatment is not causing a problem with your kidneys or liver only if your doctor thinks they are required. This will be sent to your hospital laboratory. Any surplus blood from these tests will be destroyed. This will either be taken at your GP surgery or at the hospital.
- Continue to carry out **weekly** breathing tests at home throughout your participation in the study. You should complete breathing tests daily for up to the next 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 as some questionnaires are only one question long.

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 check if there have been any changes to your medications, ask if you have experienced any side effects since the last measurement time and discuss how you are getting on with the spirometer. Questionnaires will either be posted to you (with a freepost envelope to return once completed) or you will receive a link to complete them electronically, depending on your preference. 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.

In addition, if you agreed to wear the cough monitoring device 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 research team will carry out video call to help you fit the monitor(s) and start the recording(s). A member of the Norwich Clinical Trials Unit trial team will contact

you to arrange couriers to deliver the monitors to you at home and collect them at the end of the monitoring period (packaging will be provided).

At the 12 month measurement time if you attend the hospital in person, we may also take 20mls of blood to analyse the biomarkers in it to provide information on idiopathic pulmonary fibrosis and the trial treatment in future ethically approved studies (a total of up to 30mls of blood will be taken at this visit), if you provide consent for us to do so.

At the 12 month measurement time, we will ask you to return the home spirometer and smartphone/tablet provided. A member of the Norwich Clinical Trials Unit team will contact you to arrange a courier to collect it. Packaging will be provided if needed.

What will I have to do?

We ask that you:

- Complete breathing tests, at home using the equipment provided, as directed
- Take the study medication as directed (described below)
- Keep the study medication at room temperature (under 25°C)
- Attend the study visits or phone/video calls as described above
- Carry a card explaining you are in the study and show it to your doctor whenever you consult him or her
- Contact the study team at your hospital, your hospital consultant or family doctor if you are thought to experience/are diagnosed with:
 - Chest infections including pneumonia
 - Diarrhoea
 - Or if your doctor tells you the magnesium levels in your blood have changed

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 widely used throughout the world for approximately 25 years.

You will be asked to take 2 capsules (containing either 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 and are unable to continue taking the study medication, we ask that you contact your doctor (details at the end of this leaflet) to discuss it. There may be an opportunity for you to reduce the dose of the study medication to 1 capsule (15mg) of lansoprazole or placebo twice per day (12 hours apart), 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 your clinician advises for any other reason or after discussions with your clinician.

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 and these include: atazanavir, ketoconazole, itraconazole, tacrolimus, fluvoxamine, methotrexate. Your doctor will review

the medicines you are taking before and during your time on the study to ensure you are not taking anything that might interact with the study medication. Participants taking warfarin, digoxin and/or theophylline may have extra monitoring through blood tests during the trial as an extra safety precaution.

Many patients are prescribed proton pump inhibitors like lansoprazole as anti-acid treatments without any clear benefit. If you receive these treatments, and wish to be enrolled in the study, you will be offered the opportunity to complete a two week withdrawal period if it is safe to do so. During this time, you will no longer take proton pump inhibitors and we will closely monitor you over two weeks to check if your reflux symptoms return. If they do not return after the two week period, you will be able to enter the study. If they do return, you will be able to recommence your medication but will not be able to participate in the trial. The withdrawal period will be overseen by the hospital after discussing it with your GP. All other prescriptions will remain unchanged. If you have any questions on this, please contact either your hospital doctor or the doctor in charge of this study (Professor Andrew Wilson, see section 7). You are still permitted to take over the counter anti-acid treatment such as Rennie's, Gaviscon etc. throughout the trial.

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 throughout the study.

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 (placebo) but you will still receive any approved treatment for idiopathic pulmonary fibrosis from your doctor.

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

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 at the most. You may experience the side effects mentioned above.

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 may still be useful and 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 from this study will improve our ability to treat patients with idiopathic pulmonary fibrosis in the future.

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 at the end of the study. 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 he or she may decide to prescribe this or something similar.

The results of the study will be published in scientific journals and presented at scientific meetings. You will not be named or identified in any way in any report of the study. If you would like information about the results of the study, 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 that has become available and discuss what this means for you. 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 have a concern 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 then 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 in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled with the strictest confidence. 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 data (your questionnaire information, samples and clinical 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 their behalf on the app associated with the home spirometer. 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 smart phone/tablet provided to the research team. This data will be held for 25 years before being securely disposed of. Spirometry app terms and conditions found at: <https://www.activ8rlives.com/mwdownloads/download/link/id/21>

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 also use the 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 sub-study 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. Cough study recordings will be kept for 25 years before being securely disposed of.

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 also acts, with the BTS, spirometer providers, Manchester University NHS Foundation Trust and Vitalograph, 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 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 the other researchers comply with legal, data protection and ethical guidelines.

If you join the study, the data collected for the study, together with any relevant medical records, may be looked at by authorised persons from the University of East Anglia, 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, trial drug manufacturers and courier(s) to arrange delivery of trial medication and equipment. The Norwich Clinical Trials Unit team will also receive a copy of your signed consent form. These contact details will also be shared with a courier to facilitate the shipment and return of the study supplies kit and the cough / activity monitoring device(s) (if applicable) to the Norwich Clinical Trials Unit team. 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.
- Email address – will be shared with the Norwich Clinical Trials Unit team only if you wish to consent to participate electronically, receive the study updates or opt to complete questionnaires electronically.

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 hold about you. If you agree to take part in this study, you will have the option for us to use your anonymous data and blood samples in future research. The blood samples saved from this study will be stored at Norwich Research Park Biorepository.

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 and The University of East Anglia. The study is being co-ordinated by the Norwich Clinical Trials Unit. The research is being funded by the National Institute for Health Research (NIHR), Health Technology Assessment (HTA) NIHR reference number: 127479.

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 given favourable opinion 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). You can receive general information about participating in research from your doctor.

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. Participation in the Genetic Research & Cough study

Genetic Research

If you agree to participate in the study you will also be invited to participate in the genetic part of the study. 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. For comparison, 10mls (2 teaspoons) of blood is taken routinely for safety checks. Your sample will be given a code in the same way as for the rest of your data (as described above) so only the researchers and your doctors can link it back to you. Samples will be collected and shipped to Norwich Research Park Biorepository for analysis. Analysis of these samples may be undertaken after completion of the study.

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. If you decide not to take part or to withdraw your consent for the genetic part of the study, you do not have to give a reason and there will be no change to your medical treatment or to your participation. If you withdraw from the genetic research, your sample will be destroyed and the researchers will only keep any study information collected/generated up to that point. If you withdraw from the study, you can choose whether to have your genetic sample destroyed or not.

The purpose of these analyses is not to provide a diagnosis for you. Results from the genetic analyses will not be used to prove any disease-causing genes which may carry any risk of disease for you or your close relatives. The intention is to determine genetic associations related to idiopathic pulmonary fibrosis or response to or side effects from trial treatment.

TIPAL Cough Study

If you take part in the cough sub-study, a researcher will supervise you attach a sticky pad to your chest containing a small microphone during a video call with a member of the research team. This will ensure the monitors are fitted correctly and provide an opportunity for the team to answer any questions you may have. The monitor itself will be kept in a 'bumbag' around your waist. You must not get the monitor wet. Once the monitor is fitted, you will be able to continue your daily activities. The monitor should be worn for 24 hours.

Although the monitor is designed to record the number of times you cough over 24 hours, it will record activities going on around you whilst you are wearing it. This includes the speech of you and those around you, 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 then be listened to by a trained research at Manchester University NHS Foundation Trust who will be able to 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 wrist-based 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.