

John Hunter Hospital

Respiratory and Sleep Department

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**Participant Information Statement**

**A study to investigate whether inhaled furosemide relieves cough and breathlessness in patients with interstitial lung disease.**

**Investigators:**

**Dr Emily Dunn (John Hunter Hospital)**

A/Prof Chris Grainge (John Hunter Hospital and HMRI)

Dr Geoffrey Tyler (John Hunter Hospital)

Interstitial Lung Diseases are group of disorders that cause fibrosis of the lung. This can be thought of as scarring, which causes the lungs to be stiffer and makes it difficult for oxygen to cross through the lung tissue into the blood stream. This often leads to a dry cough and chronic breathlessness.

Unfortunately there are few medications that can treat this cough and breathlessness, however some early research has shown that a medication called furosemide may help to relieve breathlessness when it is inhaled. We want to see if inhaled furosemide improves breathlessness and cough in people with interstitial lung disease.

You are being asked to participate in this study because you have interstitial lung disease. It is important to understand that while this research will help us to know more about what may help people with interstitial lung disease in the future, participating in this study will not help you with your disease currently, may not provide you with any relief of your symptoms, and will not change your ongoing treatment.

This consent form gives you important information about this study to help you decide if you want to participate. It describes the purpose of this study, the study procedures, the possible risks, and provides information about your rights as a study participant.

Please take the time to read this information carefully. You should talk to the study doctor and their study staff about this study and ask any questions you have. If you decide that you would like to participate in this study, you will be asked to sign and date this form. You will receive a copy of the signed form. After you sign this form, the study doctor and their study staff will ask you some questions to see if the study is suitable for you.

1. **WHAT YOU SHOULD KNOW ABOUT THIS STUDY**

**How long will this study take?**

This study involves two visits to hospital at least three days apart. Each visit will take approximately 1.5 hours.

**This study involves:**

* A doctor asking you questions about your health and examining you.
* Simple breathing tests and recording of observations (heart rate, blood pressure, oxygen level and breathing rate).
* Using a device called a ‘cough monitor’, which is a microphone and small recorder put on you to record the number of times you cough.
* Having a dose of an inhaled liquid through a nebuliser. One dose will be the medication we are testing (furosemide) and the other will be salty water. You will not know which you are getting, nor will the study team.
* Performing a 6 minute walk test. After the 6 minute walk test we will monitor you for another 30 minutes, during which time we will ask you regularly to show us how breathless you feel using two different scales.
* Repeating breathing tests to make sure your breathing has returned to normal.
* After you go home, we will ask you to indicate how breathless you are and how bad your cough is every hour for the next 6 hours and also to keep the cough monitor on for 6 hours.
* A second visit to hospital, repeating the above, but being given the liquid that you didn’t receive the first time. After the second visit we ask that you return the cough monitor and cough/breathlessness scores to us in person or by post.

***Spirometry:*** A breathing test that consists of blowing into a machine that measures how much air can be inhaled into the lungs and how fast it can be blown out. Performing this test will help us to see how well your lungs work normally, and make sure that your breathing is back to normal at the end of each visit before you go home.

***6 Minute Walk Test:*** The aim of the 6 minute walk test is to walk as far as you can in 6 minutes. In this study we are using the 6 minute walk test to see if the study medication can either help you walk further or recover quicker from that walk.

***Inhaling Nebulised Medication***: A nebuliser makes liquids into a fine mist which can then be inhaled. We will ask you to have both a dose of the study medication (furosemide) and a dose of salty water through a nebuliser on separate occasions.

**Can I leave the study for my own reasons?**

You can leave the study and have no more contact with the study doctor or the study staff for study-related procedures or questions at any time.

1. **SAFETY – POTENTIAL RISKS AND DISCOMFORTS**

**Are there any risks from taking part in this study?**

* **Lung Function Tests:** Occasionally some people experience dizziness, chest tightness or shortness of breath, but this is usually temporary. You know your reaction to these tests as you will already have had them in the past.
* **6 Minute Walk Test:** The 6 Minute Walk Test will make you breathless and as you have a lung disease, your oxygen levels may drop, as they may do when you exercise in your everyday life. Very occasionally people get chest pain or light headedness during the test, if this happens you should tell the study team, and the test will be stopped.
* **Inhaled Furosemide:** Tablets and injections of furosemide are very commonly used in Australia for people with heart failure to make their kidneys produce more urine. Although you will be breathing in the medication, it may still cause you to urinate a little more than you would have normally. People with other lung diseases who have been given inhaled furosemide in other studies had no other problems or side effects.
1. **POTENTIAL COSTS/REIMBURSEMENTS**

You will not be paid for your participation in this study, but you will be reimbursed for any expenses you incur. Parking expenses at the John Hunter will be reimbursed (or free parking will be organized at the HMRI building). You will not be paid for the use of your data or any information obtained from you.

1. **CONFIDENTITALITY**

Here, '**Personal Information**' means:

* All the personal information about you (including medical information) that is made available to or collected by the study doctor or their study staff throughout the course of the study, and any information derived from this information; and
* Other records containing your personal information collected or held by your treating medical practitioner/s (which may contain medical information) that is relevant to your participation in the study.

All the Personal Information collected about you (including the results of your spirometry, 6 minute walk tests, cough recordings, cough scores and breathlessness scores) will be kept confidential as outlined below. Your information will be recorded and the records will contain information such as a unique identification number, your date of birth and initials, but not your name, address or telephone number.

All data files will be coded using a unique code number. Only the study doctor and study staff will have the ability to link this code to you. The analysis results will only be linked to this code.

This study involves wearing a recording device (cough monitor). Whilst the purpose of this is to record your coughing, it will also record other sounds, including speaking. The majority of the recording will be analysed by a computer program, however the first part of the recording (done in hospital) is listened to by a person, who teaches the program to identify when you are coughing. The person listening to the recording will be someone who is not involved in your medical treatment in any way.

In accordance with Australian privacy and other relevant laws, you will be able to request access to your personal information and to correct any inaccuracies recorded. You can discuss the issue further with Dr Chris Grainge or Dr Emily Dunn at the John Hunter Hospital. With your permission, your General Practitioner, if applicable, will be informed of your participation in the study. The results of the study may be published and all reasonable steps will be taken to de-identify your personal information. All participants’ personal information will be accessed, used and stored in accordance with Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002 and the Privacy Principles in that legislation. By signing this form, you authorise the collection, storage, use and disclosure of the information collected about you as described in this section.

1. **COMPENSATION FOR INJURY**

**What do you do if you think you have an injury/illness related to your participation in this study?**

If you think you have an injury/illness that is related to the study, you should immediately notify Dr Chris Grainge or Dr Emily Dunn, the study doctors, through the John Hunter Hospital on 49 21 3000. Out of hours, phone this number and ask the switchboard team to put you through to Dr Chris Grainge. If you feel significantly unwell, also do what you normally would do, for example phone an ambulance or come to the hospital Emergency Department.

**Who can answer your questions?**

If you have any questions about this study at any time, contact the study team as above.

**Complaints Statement**

This research has been approved by the Hunter New England Human Research

Ethics Committee of Hunter New England Local Health District: 2019/ETHJ00651

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager Research Ethics & Governance Unit, Hunter New England Human Research Ethics Committee, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02)49214950, email HNEHREC@health.nsw.gov.au;



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**YOUR CONSENT TO TAKE PART IN THIS STUDY**

By signing your name below you consent to your participation in the study and you confirm the following:

* You have read this form and the study has been explained to you.
* You have been given a chance to ask any questions about this study and your questions have been answered.
* You agree to participate in the study and you acknowledge that you may leave the study at any time without penalty or loss of any benefits to which you are otherwise entitled.
* You authorise access to your medical records and information as described in this form.
* You do not give up any of your own legal rights by signing this form.

Your full name and date of birth:

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Name (PRINT) Date of birth

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Signature Date

On behalf of the research team:

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Name (PRINT)

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Signature Date