Participant Information Sheet

Effect of HFNO on Exercise Tolerance in Patients with Interstitial Lung Diseases during a Constant Work Rate Cycle Test Compared with the Effect Obtained using Oxygen through Nasal Cannula.

You are being invited to take part in our research study. Before you decide if you would like to take part, it is important for you to understand why this research is being done and what it involves. Please take your time to read this information sheet carefully. A member of our research team will also go through this information sheet with you when you attend assessment for this study and will answer any questions you have regarding participation. You may also discuss with you general practitioner if you wish.

1. What is the background and purpose of this study?

We know that patients who suffer from ILD (Interstitial Lung Disease) decline their levels of oxygen in the blood when they do physical activity, leading to reduced ability to carry out the daily activities. Pulmonary rehabilitation is a treatment for patients with ILD but fall in oxygen levels is a barrier to achieve good results from this treatment. For this reason we want to evaluate if High Flow Nasal Oxygen (HFNO), which can deliver high flows of oxygen improves the exercise capacity during an exercise test on a bicycle. This may constitute an alternative to deliver oxygen during pulmonary rehabilitation that may lead to better results of the treatment

2. Why have I been invited?

You have been invited to participate in this study because you have been diagnosed with ILD. This study will involve a total of 20 participants.

3. Do I have to take part?

No, it is completely up to you to decide if you would like to take part or not. We will go through this information sheet with you again at your pre-study assessment. If you wish to participate you will be asked to sign an Informed Consent Form. Your general practitioner will also be informed of your participation if you agree. However, you are free to change your mind at any time during the study without giving a reason. If you decide not to participate, your usual medical treatment and care will not be affected in any way, or your legal rights.

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

If you decide to participate in this study, you will be asked to read carefully and sign the Informed Consent Form. A copy of the signed form will be given to you to take away and refer to later.

Our study will run for only 2 days (see flowchart 1). During the first day height and weight will be taken.

The following measurements will also be conducted:

Spirometry, your lung function will be examined by this simple breathing test, where you will be seated and given up to 4 puffs (up to 400 micrograms) of salbutamol inhaler. After about 15 minutes, you will be asked to blow hard and fast into a tube for as long as you can. It is the same procedure as the one you have done in outpatient clinic.

During the first day, you will be asked to carry out a maximal exercise test on a bicycle called Cardiopulmonary Exercise Test (CPET) (see figure 1). We will get you on the bicycle first, just breathing for 1 minute before we start you exercising and then there will be a warm up period of 3 minutes easy pedalling before we start increasing the workload as though you were going up a hill. We want you to really push yourself and do as much as possible. The workload progressively increases, and the test is completed when you are too breathless to continue. The purpose of this test is to measure how much time your lungs and heart are able to do exercise.

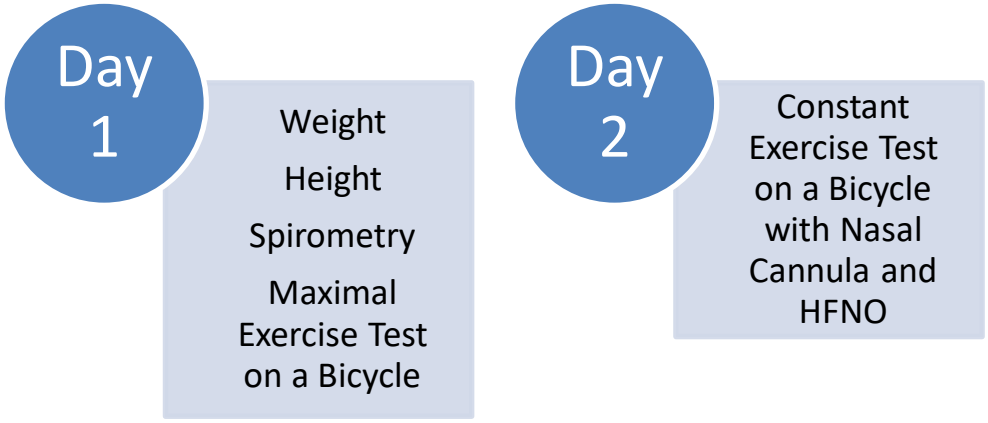
During the second day, you will undergo two exercise tests on a bicycle, but this time the workload will be constant, (75% of the maximal work load obtained from the maximal exercise test conducted the day before) separated by 60 minutes. Patients will receive randomly oxygen delivered via nasal cannula or HFNO using sealed letters, according to this some participants will first receive oxygen through HFNO and then through a nasal cannula and vice versa.

The main difference between these 2 systems is that nasal cannula can deliver low flows of oxygen, whereas HFNO can deliver high flows of oxygen, moreover HFNO will be delivered at 37°C. Participants that find too warm this temperature can receive HFNO at 34°C. The resistance of the bike (load) will no change throughout these tests and you will cycle until you feel that you need to stop. We will be measuring the minutes you are able to exercise. If you want to stop the procedure prematurely, you can do it.

During all these tests, you are going to be doing a bicycle exercise test while we monitor your heart rate oxygen levels and blood pressure. You will have electrodes on your chest to monitor your heart, a blood pressure cuff on your arm for your blood pressure, a small clip on your ear lobe or finger to monitor your oxygen saturation.

Figure 1: Cardiopulmonary Exercise Test (CPET)

Flowchart 1



5. What are the possible risks and disadvantage of taking part?

During a CPET you might experience the following: breathlessness or leg fatigue. You can stop the test at any time. Other more unfrequent symptoms may develop during exercise such as chest pain, drop in blood oxygen levels, drop or increment in your blood pressure. We will be monitoring these and we may decide to stop the test if we feel this is a risk. A clinician will be available to deal with any problem

6. What are the possible benefits of taking part?

The information gained from your participation may enable us to come up with the most optimal rehabilitation programme in the future, and this may benefit patients with ILD. Your results from the assessments we perform will also be made available to you and your general practitioner with your consent. We will inform you and your GP if anything with clinical relevance is found.

7. What will happen if I do not want to carry on with the study?

You can stop at any point, but we will keep your data that has been collected up to the point of your withdrawing but no further data will be collected. This simply means that you will no longer be attending further research clinics or taking any further active part in the research. But you will still receive your usual care.

8. What will happen when the study finishes?

When the study is completed according to plan, the results may be published in scientific or medical journals or be presented at conferences and written up as part of a doctorate. Data will be stored in a long term archive facility in the Royal Infirmary Hospital during 3 years. Participants will get a copy of their results through newsletters.

9. Expenses and payment?

You will not receive any payment for participation in this study. However, any reasonable travel and parking costs incurred by your participation in this study can be reimbursed. Please kindly keep any valid receipts for your claim.

10. Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

11. How will we use information about you?

We will need to use information from your medical records for this research project. This information will include your initials and CHI number. People will use this 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.

12. 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. 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.

13. 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/
- Our leaflet available from **www.hra.nhs.uk/patientdataandresearch**
- By asking one of the research team
- By sending an email to roberto.rabinovich@ed.ac.uk
- By ringing us on 0131 242 9198 .

Data Protection Officer contact information:

University of Edinburgh
Data Protection Officer
Governance and Strategic Planning
University of Edinburgh
Old College
Edinburgh
EH8 9YL
Tel: 0131 651 4114

NHS Lothian
Data Protection Officer
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 465 5444

14. What if there is a problem?

If you have a concern about any aspect of this study please contact Dr Roberto Rabinovich (Details below) who will do their best to answer your questions.

In the unlikely event that something goes 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 NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

15. Who is organising and funding the research?

This research study is sponsored by the University of Edinburgh and NHS Lothian and financed by a Chilean studentship called "Becas Chile"

16. Who has reviewed the study?

The study proposal has been reviewed by the research group of this study. All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from <insert REC name>. NHS Management Approval has also been given.

17. Contact for further information

In case of any questions, please feel free to contact:

Dr Roberto Rabinovich will be pleased to answer your questions.

Tel: 0131 242 9198 E-mail: **roberto.rabinovich@ed.ac.uk**

The University of Edinburgh, Queen's Medical Research Institute,

47 Little France Crescent, Edinburgh, EH16 4TJ

18. Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact:

Dr Adam Marshall. Consultant in Respiratory Medicine.

Adam.Marshall@nhslothian.scot.nhs.uk

07890809085

19. Complaints

If you wish to make a complaint about the study please contact:

Patient Experience Team

2 – 4 Waterloo Place, Edinburgh, EH1 3EG

feedback@nhslothian.scot.nhs.uk

0131 536 3370

You will be given a copy of the information sheet and a signed consent form to keep. Thank you for taking this time to consider participating this study.