

# Abnormal diffusion capacity of the lung on exercise in patients with high blood pressure in the blood channels of the lung also known as pulmonary arterial hypertension

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## Plain English summary of protocol

### Background and study aims

A person's gas transfer refers to the body's ability to transfer the oxygen that we breathe into the bag part of our lungs and transfer that through the membrane inside our lungs (known as our alveoli) and then into our bloodstream.

In a clinical setting, pulmonary function tests (PFT) are routinely performed every day around the world to assess the mechanical functions of our lungs. A PFT is a series of different breathing tests also known as the lung NCT. A PFT is completely safe and involves the patient's breathing in and out of a tube from a seated position at maximal effort. Depending on the type of breathing test the patient will be required to breathe in and out of a tube at different speeds and patterns and breathing in different gas mixtures. One of these tests is known as DLco measurement which measures gas transfer.

Patients with high blood pressure in the blood channels of the lung also known as pulmonary arterial hypertension (PAH) routinely have gas transfer measurements performed to help their respiratory physicians determine the severity of their condition. Patients with PAH tend to have abnormally low gas transfer measurements (low DLco).

The aim of this study is to see what changes occur in gas transfer measurements in PAH patients from rest to immediately when they stop exercise. Previous research has indicated that in healthy patients gas transfer should increase after exercise but no research has been conducted to determine what happens to a PAH patient's gas transfer after exercise. The reason for this avenue of investigation is to hopefully help clinicians better understand PAH which may lead to further studies that can help diagnose PAH quicker or be treated more effectively.

### Who can participate?

Patients with PAH and healthy volunteers, aged 18-65 years

### What does the study involve?

The exercise that the participants will be required to perform for this study is an incremental shuttle walk test (ISWT). The walk test will involve the patient walking between two cones

spaced 10 metres apart from each other. The patient will have to follow the auditory beeps played on an app and walk at that pace between the two cones (10 metres). There are 12 cycles each cycle lasting for 1 minute. The patient walks for as long as they can until they finish it, are too breathless to continue or can no longer keep up with the beeps, at which time the test ends.

What are the possible benefits and risks of participating?

The ISWT is used to assess PAH patients' exercise capacity in standard practice around the world and is extremely safe.

Where is the study run from?

Mater Hospital (Ireland)

When is the study starting and how long is it expected to run for?

November 2023 to December 2024

Who is funding the study?

Mater Hospital (Ireland)

Who is the main contact?

Dr Ciara McCormack, [ciaramccormack250@gmail.com](mailto:ciaramccormack250@gmail.com)

## Contact information

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Public, Scientific

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

1

## Study information

### Scientific Title

A pilot study: impaired pulmonary diffusion capacity on exercise in patients with pulmonary arterial hypertension

### Study objectives

The alternative hypothesis of the study is that the patients in group 1 with pulmonary arterial hypertension (PAH) will have a significantly lower percentage change in diffusing capacity for carbon monoxide (DLCO) from their baseline to immediately following exercise when compared to the age-matched control group.

The null hypothesis of the study is that the patients in group 1 with PAH will have a significant increase in percentage change in DLCO from their baseline to immediately following exercise when compared to the age-matched control group.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 14/02/2024, Mater Misericordiae University Hospital REC (Dublin, Dublin, 000, Ireland; N/A; hannahking@mater.ie), ref: 1/378/2407

### Study design

Single-centre prospective observational proof of concept study

### Primary study design

Observational

### Study type(s)

Efficacy

## Health condition(s) or problem(s) studied

Pulmonary hypertension

## Interventions

The study will involve recruiting PAH patients on PH-specific targeted therapies and ten age-matched healthy controls who will complete baseline pulmonary diffusion capacity measured at rest and immediately after completing the incremental shuttle walk test (ISWT).

## Intervention Type

Other

## Primary outcome(s)

Change in DLCO immediately (within 1-2 min) following exercise (DLCO at maximum exercise minus DLCO at rest) measured by modified Kroghs single breath method

## Key secondary outcome(s)

1. Cardiac effort: total number of heartbeats divided by the total distance travelled in the incremental shuttle walk test (ISWT)
2. Heart rate reserve at the end of exercise (maximum heart rate minus resting heart rate)
3. % of maximum predicted heart rate (maximum heart rate divided by  $220 - \text{Age}$  in years multiplied by 100)
4. % of maximum predicted walk distance achieved at the end of exercise ( $\text{ISWT}_{\text{pred}} = 1449.701 - (11.735 \times \text{age}) + (241.897 \times \text{gender}) - (5.686 \times \text{BMI})$ , where male gender = 1 and female gender = 0)  
Total walk distance achieved (m)/predicted walk distance (m) x 100
5. Heart rate recovery in the first minute immediately after the end of exercise (maximum heart rate - heart rate after 1 min of having stopped exercise)
6. Change of oxygen saturation immediately before the end of exercise (oxygen saturation at rest - minimum oxygen saturation achieved just before the end of exercise)
7. Calculated peak oxygen consumption at the end of exercise ( $\text{VO}_2 \text{ peak (predicted)} = 19.793 + (0.02 \times \text{distance walked}) - (0.236 \times \text{age})$ )
8. Change in DLCO/heart rate slope between rest and exercise (DLCO at rest / resting heart rate minus DLCO at peak exercise / maximum heart rate achieved)
9. Breathlessness measured using modified Borg score immediately at the end of exercise
10. Body weight (kg) x distance (m) product measured at the end of exercise
11. Quality of life measured using the Emphasis 10 scale at the start of the trial

Devices used to collect measures:

PFT System: Vyntus ONE PFT system

ISWT: Vyntus walk tablet with Spo2

Spo2/HR: Nonin Pulse Oximeter

## Completion date

10/12/2024

## Eligibility

### Key inclusion criteria

Group 1 PAH:

1. Patients with diagnosed idiopathic pulmonary artery hypertension (IPAH)/drug-induced

pulmonary artery hypertension (DPAH)/heritable pulmonary arterial hypertension (HPAH) /connective tissue disease (CTD) PAH who are stable for the past three months on PH-specific targeted therapy.

2. Normal spirometry

3. No evidence of interstitial lung diseases (ILD)/emphysema on CT scan

4. Never smokers or ex-smokers with less than equal to 10 pack years h/o smoking

5. Age 18-65 years

Age-matched controls:

1. No h/o cardiovascular disease

2. BMI <25 kg/m<sup>2</sup>

3 Never smoker

4. Normal spirometry

5. Do not currently meet the recommended physical activity government guidelines of at least 150 minutes of moderate-intensity aerobic activity per week

6. Age 18-65 years

### **Participant type(s)**

Healthy volunteer, Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

65 years

### **Sex**

All

### **Key exclusion criteria**

1. Unable to provide written consent

2. Unable to perform the incremental shuttle walk test

3. Pregnant and breastfeeding mothers

4. Healthy volunteers with abnormal pulmonary function test (PFT) data

5. Control group or PAH patients who cannot obtain two reproducible baseline DLCO measurements within three attempts

### **Date of first enrolment**

15/03/2024

### **Date of final enrolment**

29/06/2024

## **Locations**

## Countries of recruitment

Ireland

## Study participating centre

**Mater Misericordiae University Hospital**

Dublin

Dublin

Ireland

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## Sponsor information

### Organisation

Mater Hospital

### ROR

<https://ror.org/050batv17>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Mater Hospital

## Results and Publications

### Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary

Stored in non-publicly available repository, Data sharing statement to be made available at a later date