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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

Submission date
16/02/2024

Recruitment status
No longer recruiting

Registration date
26/02/2024

Overall study status
Completed

Last Edited
26/02/2024

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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?
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Contact information

Type(s)
Public, Scientific

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Additional identifiers

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

Primary study design
Observational

Study design
Single-centre prospective observational proof of concept study

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-Age in years multiplied by 100)
4. % of maximum predicted walk distance achieved at the end of exercise (ISWTpred = 1449.701 – (11.735 × age) + (241.897 × gender) – (5.686 × 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 (VO2 peak (predicted) = 19.793 + (0.02 x distance walked)-(0.236 x 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/m²
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
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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