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Habitual physical activity and exercise capacity in pulmonary hypertension

Submission date
09/02/2015

Recruitment status
No longer recruiting

Registration date
30/03/2015

Overall study status
Completed

Last Edited
26/05/2021

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Pulmonary hypertension (PH) is a serious health condition caused by raised blood pressure within the pulmonary arteries (the blood vessels going to the lungs). It can result in damage to the right side of the heart, so that it isn't able to pump blood around the body as well as it should. PH is a debilitating disease with symptoms including shortness of breath, fatigue, feeling faint and dizzy, chest pain and tachycardia (irregular heart beat). The condition can have severe effects on a person's quality of life. As the symptoms are non-specific and possibly due to a number of other causes, diagnosis of PH and referral to appropriate specialists can be delayed resulting in worsening of the patients condition. Management of PH focuses on both supportive therapy and target driven drug therapies. Support management includes diuretics, oxygen, and digoxin (a heart drug). Modern drug therapy has led to a significant improvement in patient symptoms and has slowed the rate of clinical deterioration. Exercise training in number of recent studies has been shown to be beneficial in improving quality of life and increase the amount of exercise the patients can do (exercise capacity). Despite the use of medications and exercise, patients remain symptomatic with a poor quality of life and prognosis. Recent clinical studies have shown that PH leads to weakness of the muscles and leads to both an increase in muscle protein breakdown and changes in muscle fibre types. We need greater understanding of the effect of currently accepted treatment for PH on a patients physical activity and ability to exercise. Only then can we focus on the role of resistance training in improving symptoms and function in PH patients. Mitochrondria are found within cells and generate energy for cell function. This study will involve research into the function of muscles of PH patients and activity of mitochrondria in muscle cells using a functioning imaging technique.

Who can participate?
Adults (aged over 18) diagnosed with PH.

What does the study involve?
Participants undergo a course of targeted pulmonary hypertension therapy. During this time they are asked to complete two questionnaires at different points in the study. They also wear an accelerometer and do a cardiopulmonary exercise test at the start of the study, after 3

months and then after 6 months. We look closely at how muscles extract and use oxygen over a time course of standard care. This study will help us develop potential new exercise rehabilitation programme particularly the role of resistance training in pulmonary hypertension.

What are the possible benefits and risks of participating?
There are no risk from wearing the accelerometer. Cardiopulmonary exercise testing will be supervised in a hospital and is considered a relatively safe procedure to undergo in patients with pulmonary hypertension, with rare risk of arrhythmia arising requiring treatment.

Where is the study run from?
Newcastle upon Tyne NHS Foundation Trust, Freeman Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2015 to February 2017

Who is funding the study?
Newcastle upon Tyne Hospitals NHS Trust (UK)

Who is the main contact?
Dr Sasiharan Sithamparanathan

Contact information

Type(s)
Scientific

Contact name
Dr Sasiharan Sithamparanathan

Contact details
Newcastle upon Tyne NHS Foundation Trust
Freeman Hospital
Newcastle
United Kingdom
NE7 7DN

Additional identifiers

Protocol serial number
7374

Study information

Scientific Title
Habitual physical activity and exercise capacity in pulmonary hypertension: a pilot study

Study objectives
Habitual physical activity and exercise capacity increases with targeted treatment for pulmonary hypertension.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Westminister, 30/01/2015, ref: 15/LO/0144

Study design
Single-centre pilot study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pulmonary hypertension

Interventions
All patients deemed necessary will undergo initiation of targeted pulmonary hypertension therapy. They will be followed up at baseline, 3 and 6 months with quality of life scores, monitoring their activity levels and undergoing cardiopulmonary exercise tests.

Intervention Type
Drug

Phase
Not Applicable

Primary outcome(s)
The change in peak oxygen consumption (VO2) with PH specific treatment.

Measured at baseline, 3 and 6 months

Key secondary outcome(s))
1. Change in habitual physical activity levels with treatment.
2. Change in cardiac output and peripheral muscle oxygen extraction during exercise with PH-specific treatment.

Measured at baseline, 3 and 6 months

Completion date
28/02/2017

Eligibility

Key inclusion criteria

1. Patients' aged greater than 18 years
2. Underlying diagnosis of pulmonary hypertension confirmed by the National Pulmonary Hypertension Service(Newcastle)
3. World Health Organization (WHO) functional Class II to IV

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients who are unable to provide informed consent
2. Patients with recent syncope
3. Patients with known skeletal and muscle abnormalities
4. Patients with ischaemic heart disease

Date of first enrolment
01/03/2015

Date of final enrolment
30/11/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Newcastle upon Tyne NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle-upon-Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Newcastle upon Tyne Hospitals NHS Trust

Alternative Name(s)
Newcastle upon Tyne Hospitals NHS Trust

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes