ISRCTN64759523 https://doi.org/10.1186/ISRCTN64759523

WP4 Exercise Outcome Study: a comprehensive comparison of the sensitivity of common exercise outcome measures for chronic obstructive pulmonary disease (COPD)

Submission date
17/05/2013

Recruitment status
No longer recruiting

Registration date
17/05/2013

Overall study status
Completed

Last Edited
14/11/2018

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There are many exercise tests available that can measure how limited a person's activities are with Chronic Obstructive Pulmonary Disease (COPD). These exercise tests are also commonly used to measure improvements following therapies such as inhaled medications and rehabilitation programmes. The exercise tests vary a great deal and range from laboratory based systems through to tests requiring little equipment. This study aims to conduct an in depth comparison of the most frequently used exercise tests used to assess functional capacity in patients with COPD. This study looks at the exercise tests before and after a 6 week intervention (treatment) of either inhaled medication, pulmonary rehabilitation or no intervention (control group). The study compares the overall change in the test measures performed before and after the intervention. It is hoped that the results of this study will provide a greater understanding of how good the tests are at measuring results from an intervention, to guide further studies and clinical practice.

Who can participate?
Patients aged 40 - 85 with a diagnosis of COPD who walk slower due to breathlessness, or have to stop for breath when walking at their own pace

What does the study involve?
Participants undertake two laboratory based cycle tests and five other tests including three walking tests, one leg strength test and one test measuring physical performance (i.e. balance and standing from a chair). The study involves 5 visits to the hospital over a period of approximately 7-9 weeks. Participants are randomly allocated to one of the three groups to receive 6 weeks of an intervention followed by two further visits for final data collection. Group 1 receive inhaled medication, group 2 receive pulmonary rehabilitation and group 3 receive no intervention (control group). Participants are also asked to wear an activity monitor at the start and end of the trial for a period of 7 days.

What are the possible benefits and risks of participating?
There are no direct benefits of participating in this study. However, by taking part in this research, people will be contributing to the development and understanding of exercise testing in COPD. If patients are allocated to the rehabilitation group they may feel a benefit from the exercise programme. For those patients who are not allocated to the pulmonary rehabilitation group, it will be offered to them at the end of the study at the discretion of the patient and their doctor. The effects and discomforts of each test are described in the patient information sheet. The risks of completing the exercise tests are very low. When completing a maximal CPET there is a possible risk of collapse due to rapid heart rate but if patients have collapsed previously when exercising they are not asked to participate. Participants may become breathless when completing all of the tests but this is not dangerous and is a normal reaction to testing.

Where is the study run from?
Glenfield Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2013 to August 2017

Who is funding the study?
The study is being funded through the Medical Research Council (MRC) and pharmaceutical industry partners

Who is the main contact?
Theresa Harvey-Dunstan
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

13643

Study information

Scientific Title
A comprehensive comparison of the sensitivity of common exercise outcome measures for chronic obstructive pulmonary disease (COPD): a randomised trial

Acronym
WP4 Exercise Outcome Study

Study objectives
The study aims to conduct a comprehensive comparison of exercise tests commonly used to assess functional capacity in patients with Chronic Obstructive Pulmonary Disease (COPD). Several exercise tests have been described for this purpose, however, there has been no comprehensive comparison of the relative reproducibility and sensitivity of these tests following a standard intervention. The study will help provide a greater understanding of the relative properties (stability and sensitivity) of these tests. The study will provide information for the regulatory bodies regarding the assessment of activity limitation in COPD for future clinical trials.

The study will compare the outcomes of the exercise tests following an effective intervention, of either pulmonary rehabilitation or an inhaled bronchodilator therapy for 6 weeks. There will also be a control arm where there is no intervention. The study aims to recruit approximately 241 patients (phase 1 n=61 and phase 2 n=78) with COPD (COPD Gold 2 4). Patients will be in the study for approximately 7 weeks, where the exercise tests will be performed prior and post intervention. The range of change in performance will be measured to enable an evaluation of the exercise tests.

Ethics approval required
Old ethics approval format

Ethics approval(s)
REC - 12/WM/0306, 22/02/2013

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Respiratory; Subtopic: Respiratory (all Subtopics); Disease: COPD

Interventions
1. Pulmonary Rehabilitation: Six week programme, twice weekly
2. Tiotropium, Exercise test sensitivity to the addition of Tiotropium
3. Control: No intervention

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Vo2 Peak measured at baseline and post Intervention

Secondary outcome measures
Work Load, Duration, Heart Rate, SpO2, Distance, Borg Breathlessness Scale, Strength (kg), Gait Speed, function scores & Health related Quality of Life.

Overall study start date
01/03/2013

Completion date
30/11/2017

Eligibility

Key inclusion criteria
Current inclusion criteria as of 25/01/2016:
1. Confirmed diagnosis of COPD (COPD Gold Stage II Gold IV)
2. MRC grade dyspnoea >2
3. Aged 40 - 85 years, male & female

Previous inclusion criteria:
1. Confirmed diagnosis of COPD (COPD Gold Stage II Gold IV)
2. MRC grade dyspnoea >3
3. Aged 40 - 85 years, male & female

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
139

Key exclusion criteria
1. Co-morbidity that limits the ability to walk/cycle (e.g. musculoskeletal, arthritic, or neurological disorders)
2. Participation in rehabilitation over the last 12 months
3. Patients on long term oxygen therapy
4. Patients requiring oxygen therapy during the course of an exercise test (i.e. de-saturation documented below 85%)

Date of first enrolment
22/03/2013

Date of final enrolment
31/08/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Glenfield Hospital
Leicester
United Kingdom
LE3 9QP

Sponsor information

Organisation
Glenfield Hospital (UK)

Sponsor details
Groby Road
Leicester
England
United Kingdom
LE3 9QP

Sponsor type
Hospital/treatment centre

Website
http://www.leicestershospitals.nhs.uk/aboutus/our-hospitals/glenfield-hospital/

ROR
https://ror.org/048a96r61

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Abstract results	interim analysis	23/12/2014		No	No