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The application of non-invasive ventilation during pulmonary rehabilitation in patients with Chronic Obstructive Pulmonary Disease (COPD)

Submission date
07/02/2013

Recruitment status
No longer recruiting

Registration date
15/02/2013

Overall study status
Completed

Last Edited
22/01/2019

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims.
People with Chronic Obstructive Pulmonary Disease (COPD) have difficulty breathing due to narrowing of their airways. Pulmonary Rehabilitation (PR) improves Quality of Life (QoL) in COPD patients. Exercise is key to this treatment, but patients with more severe COPD may not be able to train at the required level. Non-invasive ventilation (NIV) uses positive pressure applied to the face via a mask and helps more severe COPD patients to exercise. The aim of this study is to find out how practical the Trilogy Ventilator is to use and the short- and long-term effects of NIV during exercise.

Who can participate?
Men and women aged 40 and above with COPD.

What does the study involve?
Suitable subjects will be invited to take part in the study and depending on which group they are assigned to will need to attend the hospital for a maximum of four visits. Participants will be randomly allocated into one of three groups:
Group 1: Standard treatment: exercise and oxygen.
Group 2: Exercise with NIV and oxygen.
Group 3: Continued supervised exercise program, with NIV, and oxygen if indicated at home.
Participants in group 2 and 3 will use the Trilogy Ventilator as their NIV device. The Trilogy Ventilator is a portable NIV device that is able to record information on use and the patients breathing. Before being discharged from hospital subjects will be required to undergo a medical examination (to obtain information such as gender, height and weight), complete a series of questionnaires, complete some standard exercise tests and be trained on the device to be used in the study. At the second and third visit subjects will be required to complete the questionnaires again and undergo some standard exercise tests (subjects in group 1 and 2 will receive the questionnaires by post). At the final visit all groups will need to complete the questionnaires and exercise tests again and return all of the study equipment.

What are the possible benefits and risks of participating?
We believe that the Trilogy device may allow for easier ward-based exercise and patients may feel more able to participate due the benefits of exercising with NIV. Patients may then benefit from continuing to exercise with the portable ventilator at home. The use of the device will be monitored by trained clinical staff. The patient can also easily remove their interface device should it become uncomfortable or make breathing difficult.

Where is the study run from?
Bristol Royal Infirmary (UK).

When is the study starting and how long is it expected to run for?
It is anticipated that the study will start recruiting in February 2013. Each patient is in the study for 3 months.

Who is funding the study?
Philips Home Healthcare Solutions (UK).

Who is the main contact?
Mrs K Buchan (Katy.Buchan@UHBristol.nhs.uk)
Dr AH Kendrick (Adrian.Kendrick@UHBristol.nhs.uk)

Contact information

Type(s)
Scientific

Contact name
Mrs Katy Buchan

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

EAME2011Trilogy01

Study information

Scientific Title
A randomized control trial of non-invasive ventilation during an exercise programme following acute acidotic exacerbation of COPD in hospital and follow-up use at home: feasibility of using the Trilogy Ventilator

Study objectives
The use of the Trilogy Ventilator will improve health related Quality of Life in patients with Chronic Obstructive Pulmonary Disease following an acute acidotic exacerbation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West - Central Bristol. Bristol Research Ethics Committee, 24/09/2012, ref: 12/SW/0228

Study design
Randomized non-blinded controlled 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
Chronic Obstructive Pulmonary Disease

Interventions
Group 1: Standard treatment: exercise and oxygen (If SpO2 < 90%)
Group 2: Exercise with NIV (average PS 20) and oxygen (If SpO2 < 90%)
Group 3: Continued supervised exercise program, with NIV, and Oxygen if indicated at home

Visit 1. (Baseline) (All Groups)
1. Inclusion/Exclusion
2. Demographic Data (gender, age, height, weight, living situation, education level, smoking

history, alcohol use and disease co-morbidity)
3. The EuroQol questionnaire (EQ-5D)
4. The St Georges Respiratory Questionnaire
5. The London Chest Activity of Daily Living Questionnaire
6. The MRC Dyspnoea scale
7. 6 Minute Walk Test
8. Actical monitoring of exercise programme (according to randomization group)
9) Issue Diary Card

Pre-Discharge Assessment. (Baseline) (All Groups)
1. Demographic Data
2. The EuroQol questionnaire (EQ-5D)
3. The St Georges Respiratory Questionnaire
4. The London Chest Activity of Daily Living Questionnaire
5. The MRC Dyspnoea scale
6. 6 Minute Walk Test
7. Actical monitoring of exercise programme (according to randomization group)

Visit 2. Month 1 (Group 3)
1. The EuroQol questionnaire (EQ-5D)
2. The St Georges Respiratory Questionnaire
3. The London Chest Activity of Daily Living Questionnaire
4. The MRC Dyspnoea scale
5. 6 Minute Walk Test
6. Actical monitoring of exercise programme
7. Check Diary Card

Visit 2. Month 1 (Group 1 and 2 - Questionnaires via post)
1. The EuroQol questionnaire (EQ-5D)
2. The St Georges Respiratory Questionnaire
3. The London Chest Activity of Daily Living Questionnaire
4. The MRC Dyspnoea scale
5. 6 Minute Walk Test
6. Check Actical Monitor being used
7. Check Diary Card

Visit 3. Month 2 (Group 3).
1. The EuroQol questionnaire (EQ-5D)
2. The St Georges Respiratory Questionnaire
3. The London Chest Activity of Daily Living Questionnaire
4. The MRC Dyspnoea scale
5. 6 Minute Walk Test
6. Actical monitoring of exercise programme
7. Check Diary Card

Visit 3. Month 2 (Group 1 and 2 Questionnaires via post).
1. The EuroQol questionnaire (EQ-5D)
2. The St Georges Respiratory Questionnaire
3. The London Chest Activity of Daily Living Questionnaire
4. The MRC Dyspnoea scale

5. 6 Minute Walk Test
6. Check Actical Monitor being used
7. Check Diary Card

Visit 4. Month 3 (All Groups - patients either visited by researcher or reviewed in out patient clinic).
1. The EuroQol questionnaire (EQ-5D)
2. The St Georges Respiratory Questionnaire
3. The London Chest Activity of Daily Living Questionnaire
4. The MRC Dyspnoea scale
5. 6 Minute Walk Test
6. Actical monitoring of exercise programme
7. Retrieve Diary Card
8. Retrieve Equipment

Additional contact:
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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Health related quality of life (QoL) is measured using the EuroQol questionnaire (EQ-5D) (Brooks R, et al, 1996), will be used. The EQ-5D is a patient-completed questionnaire giving a single index value for health status and has been used in COPD patients (Cleland J, et al, 2007; Gonzalez-Moro J, et al, 2009; Harper R, et al, 1997; Heyworth I, et al, 2009; Nilsson E, et al, 2007; Pickard A, et al, 2008; Stahl E, et al, 2003; Stahl et al, 2005; Szende A, et al, 2009;).

The EQ-5D will be completed as follows
1. On admission to the study
2. At point of discharge home
3. At 1, 2 and 3 months of the study.

Completion of the EQ-5D at time points 1 and 2 will be supervised by the researcher. In all three groups, following discharge, the questionnaire will be posted out to the patients.

Secondary outcome measures
1. Breathlessness during Daily Activity: This will be measured using the London Chest Activity of Daily Living questionnaire (Garrod R, et al, 2002). If NIV improves the ability to exercise and

results in the patients being less breathless during exercise, daily activity should increase (Pitta et al, 2008).
2. Subjective Breathlessness: The MRC Dyspnoea scale (Burdon JG et al, 1982) will be used to assess the level of perceived breathlessness. The normal scale of 1 5 will be reduced to 3 levels Grade 1 and 2 those who are troubled by breathlessness on strenuous exertion or short of breath when hurrying; Grades 3 and 4 patient who need to walk slower than most people of their own age on level ground or to stop for breath after walking about 100 yards on the level; and Grade 5 those who were too breathless to leave the house or were breathless after undressing
3. Diary Card: We will give patients an optional symptom diary card to indicate changes in symptoms over time. It will also allow us to monitor drug usage and changes in therapy as prescribed. We will ask patients to assess cough, sputum production, breathlessness, wheeze, sputum colour, sleepiness, and activity levels, and will allow us to monitor reported and unreported exacerbations (Vijayasaratha K, et al, 2008).
4. Compliance with NIV on Exercise: Usage of NIV during exercise will be obtained from the integrated monitor from the Trilogy that records date, time, duration and other physiological data during each treatment session.
5. Activity Levels: From the ActiCal software, the levels of activity over a predefined period of time will be assessed, giving mean activity, number of steps and energy expenditure levels.
6. Demographics: In addition to recording gender, age, standing height and weight, we will ask the following information at baseline: living situation, education level, smoking history, alcohol use and disease co-morbidity.

Overall study start date
01/02/2013

Completion date
01/02/2015

Eligibility

Key inclusion criteria
1. Male and female subjects, aged 40 and above (no upper age limit)
2. Primary diagnosis of COPD
3. Admission for an acute exacerbation on chronic respiratory failure requiring non-invasive ventilation (NIV)
4. Able to mobilize following admission
5. Able to use NIV within the hospital setting during exercise
6. Not attending Pulmonary Rehabilitation or planned to within the study period of three months post discharge

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

Key exclusion criteria
1. Unable to tolerate/use NIV
2. Unable to mobilize following admission
3. Currently undertaking pulmonary rehabilitation
4. Primary diagnosis is not COPD

Date of first enrolment
01/02/2013

Date of final enrolment
01/02/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Sleep Unit
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Sponsor information

Organisation
Bristol Royal Infirmary (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.uhbristol.nhs.uk/your-hospitals/bristol-royal-infirmary.html

ROR
https://ror.org/031p4kj21

Funder(s)

Funder type
Industry

Funder Name
Philips Home Healthcare Solutions (UK)

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?
Results article	results	23/12/2014	22/01/2019	Yes	No