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Home oxygen therapy versus home mechanical ventilation for chronic obstructive pulmonary disease

Submission date
31/03/2010

Recruitment status
No longer recruiting

Registration date
31/03/2010

Overall study status
Completed

Last Edited
05/06/2017

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease (COPD) is the name for a collection of lung diseases usually caused by smoking. When symptoms become particularly bad this is called an exacerbation. Some exacerbations of COPD can be very severe and patients need support from breathing machines (ventilators) in addition to oxygen therapy. Previous studies have examined whether the use of a ventilator at home, termed home mechanical ventilation, could help improve people's breathing and reduce the need for readmission to hospital, but these studied have not been able to demonstrate a benefit. This is thought to be due to the poor design of the studies rather than failure of the ventilator itself. This study is a UK-wide study to investigate if home mechanical ventilation in addition to home oxygen therapy is better than home oxygen therapy on its own.

Who can participate?
Patients aged 18 or older who have had a life-threatening COPD exacerbation at least 2 weeks ago

What does the study involve?
Participants are randomly allocated to receive home oxygen therapy with or without home mechanical ventilation. They are followed up for 12 months to see if patients who received home mechanical ventilation have fewer hospital admissions.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
St Thomas's Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2009 to June 2016

Who is funding the study?
1. Guy's and St. Thomas' Charity (UK)
2. Respironics, Inc. (USA)
3. ResMed Ltd (Australia)

Who is the main contact?
Dr Patrick Murphy

Contact information

Type(s)
Scientific

Contact name
Dr Patrick Murphy

Contact details
St Thomas's Hospital
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SE1 7EH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00990132

Secondary identifying numbers
8059

Study information

Scientific Title
Randomised controlled trial of home mechanical ventilation in hypercapnic chronic obstructive pulmonary disease patients post acute hypercapnic exacerbation

Acronym
HOT HMV in COPD

Study objectives
The trial is designed to test the hypothesis that the use of home non-invasive ventilation (NIV) in persistently hypercapnic chronic obstructive pulmonary disease (COPD) patients following an acute hypercapnic exacerbation of COPD reduces hospital admissions and improves survival.

Ethics approval required

Old ethics approval format

Ethics approval(s)
St Thomas' Hospital Research Ethics Committee, 12/06/2009, ref: 09/H0802/2

Study design
Randomised interventional multicentre treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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

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

Interventions
1. Domiciliary non-invasive ventilation (HMV)
2. Home oxygen therapy (HOT)

Follow up length: 12 month(s)
Study entry: Single randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Admission-free survival up to 12 months

Secondary outcome measures
Measured at 6 weeks, 3 months, 6 months, 12 months:
1. Daily activity - actigraphy
2. Exercise tolerance
3. Pulmonary mechanics
4. Respiratory muscle strength
5. Sleep quality - actigraphy

Overall study start date
01/10/2009

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Acute hypercapnic exacerbation of COPD at least 2 weeks previously
2. In patient admission with acute hypercapnic respiratory failure
3. Smoking greater than 20 pack year history
4. Forced expiratory volume in one second (FEV1) less than 50%
5. FEV1/forced vital capacity (FVC) less than 60%
6. Chronic hypercapnia (PaCO2 greater than 7 kPa)
7. Chronic hypoxia PaO2 less than 7.3 kPa or less than 8 kPa with secondary polycythaemia, pulmonary hypertension, peripheral oedema or significant nocturnal hypoxia (SpO2 less than 90% for greater than 30% sleep time)
8. Aged 18 years or older, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 116; UK Sample Size: 116

Key exclusion criteria
1. Unable to wean off NIV prior to discharge (persistent hypercapnic respiratory failure with pH less than 7.30)
2. Post extubation or decanulation
3. Body mass index (BMI) greater than 35 kg/m^2
4. Primary diagnosis of restrictive lung disease causing hypercapnia
5. Development of worsening hypercapnic respiratory failure with acidosis during initiation of oxygen therapy (ABG - pH less than 7.30 taken 2 - 4 hours after waking)
6. Unable to tolerate NIV (if given) during acute illness
7. Unstable coronary artery syndrome
8. Renal replacement therapy
9. Inability to consent/comply with trial protocol (as determined by site PI)
10. Aged less than 18 years
11. Pregnant

Date of first enrolment
01/02/2010

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Thomas's Hospital
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's and St. Thomas' NHS Foundation Trust (UK)

Sponsor details
4th Floor
Thomas Guy House
Lambeth Palace Road
London
England
United Kingdom
SE1 7EH

Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk/

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Industry

Funder Name
Guy's and St. Thomas' Charity (UK)

Alternative Name(s)
Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Respironics, Inc. (USA)

Funder Name
ResMed Ltd (Australia)

Results and Publications

Publication and dissemination plan
The study will be analysed and prepared for publication in a scientific journal and presentation at international conferences such as the European respiratory congress.

Intention to publish date
30/06/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to institution policy.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
	results				

Results article	06/06/2017	Yes	No