

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

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| <b>Submission date</b><br>31/03/2010   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>31/03/2010 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>05/06/2017       | <b>Condition category</b><br>Respiratory          | <input type="checkbox"/> 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 studies 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  
249 Westminster Bridge Road  
London  
United Kingdom  
SE1 7EH

## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT00990132

### Protocol serial number

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)

## **Study design**

Randomised interventional multicentre treatment trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **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(s)**

Admission-free survival up to 12 months

## **Key secondary outcome(s)**

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

## **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 (PaCO<sub>2</sub> greater than 7 kPa)

7. Chronic hypoxia PaO<sub>2</sub> less than 7.3 kPa or less than 8 kPa with secondary polycythaemia, pulmonary hypertension, peripheral oedema or significant nocturnal hypoxia (SpO<sub>2</sub> less than 90% for greater than 30% sleep time)
8. Aged 18 years or older, either sex

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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<sup>2</sup>
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**

United Kingdom

England

**Study participating centre**

**St Thomas's Hospital**

London

United Kingdom

SE1 7EH

## Sponsor information

**Organisation**

Guy's and St. Thomas' NHS Foundation Trust (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

## 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? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               | results                       | 06/06/2017   |            | Yes            | No              |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |