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A randomised controlled trial to compare auto variable positive airway pressure ventilation with conventional non-invasive positive pressure ventilation in the treatment of hypercapnic ventilatory failure in chronic obstructive pulmonary disease

Submission date 15/06/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/06/2006	**Overall study status** Completed	
Last Edited 03/05/2011	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
P01032; National Research Register: N0542167931

Study information

Scientific Title

Study objectives
Auto variable positive pressure ventilation is as efficiacious as standard positve pressure ventilation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Huntingdon research ethics committee on 27/10/2005 (ref: 05/Q0104/118)

Study design
Randomised cross over study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
There are two groups: the first will receive either auto variable positive airway pressure ventilation (auto VPAP) and the second group will receive standard non-invasive positive pressure ventilation (NIPPV). After eight weeks the two groups will cross over. The patients will be randomised to start on either auto VPAP or NIPPV. The control group is the group receiving standard NIPPV.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Nocturnal oxygenation

Secondary outcome measures
Pulmonary function

Overall study start date
16/12/2005

Completion date
01/02/2007

Eligibility

Key inclusion criteria
1. Diagnosis of Chronic Obstructive Pulmonary Disease (COPD)
2. Forced expiratory volume in one second (FEV1) < 50%
3. Smoking history > 20 pack years
4. Hypercapnic ventilatory failure

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Age > 80
2. Body Mass Index (BMI) > 40

Date of first enrolment
16/12/2005

Date of final enrolment
01/02/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Papworth Hospital
Papworth Everard
United Kingdom
CB3 8RE

Sponsor information

Organisation
Papworth Hospital Foundation NHS Trust (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.papworthpeople.com

ROR
https://ror.org/01qbebb31

Funder(s)

Funder type
Industry

Funder Name
ResMed

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	01/12/2010		Yes	No