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The impact of changing the pressure generating device in people with sleep apnoea using Continuous Positive Airway Pressure (CPAP) less than 4 hours per night

Submission date 07/01/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/03/2010	**Overall study status** Completed	
Last Edited 05/07/2016	**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

Protocol serial number
N/A

Study information

Scientific Title

The impact of changing the pressure generating device in people with sleep apnoea using Continuous Positive Airway Pressure (CPAP) less than 4 hours per night: a randomised controlled crossover trial

Study objectives
Does changing to Bi–level positive airway pressure (Bi–level PAP) support increases usage in obstructive sleep apnoea (OSA) patients who have suboptimal compliance with fixed continuous positive airway pressure (CPAP) due to pressure intolerance?

The most effective treatment for symptomatic, moderate to severe OSA is with CPAP. To derive optimal benefit it is recommended that CPAP should be used for at least 4 hours per night. However, only 46-83 % of individuals use it for more than 4 hours every night. Different mechanical interventions (Auto positive airway pressure, Bi-level Positive airway pressure, and expiratory release positive airway pressure) have failed to show any significant improvement in compliance. Most of these studies have studied unselected subjects first initiating therapy. It is possible that subjects who after all simple measures to improve compliance have been addressed are still non-compliant may show a demonstrable improvement with a change of mode of pressure delivery. In this study we will evaluate the role of Bi-level PAP in OSA patients who remain poorly compliant with CPAP (despite appropriate interventions to improve local side effects and/or who complain of pressure related problems).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 2 Research and Ethics Committee (REC), April 2009, ref: 09/H0308/68

Study design
Single-centre two-period two-arm randomised controlled crossover group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obstructive sleep apnoea

Interventions
The study will have a two-period, two-treatment crossover randomised controlled trial design. Patients with average CPAP use less than 4 hours per night who meet the inclusion and none of the exclusion criteria will be randomised to either receive a Bi-level positive airway pressure (Bi-PAP) device first or to receive a brand of fixed CPAP machine different from the one they have used previous to entering the study. They will have a baseline measure of CPAP compliance, daytime sleepiness and quality of life. Both groups will receive a similar level of continuing clinical support by the CPAP practitioners and Respiratory Support and Sleep Centre (RSSC) nurses (24 hour telephone helpline, early clinic review and advice if there is any problem) as per the standard clinical care at our centre.
They will then be reviewed at 4 weeks with repeat measurements of compliance, sleepiness and quality of life.

For the second period, those that received CPAP in the first period will get Bi-level PAP and vice versa. They will go home with the advice to start using the new device after 2 weeks. Until that time they will stay on their initial CPAP. This will give them a washout period of two weeks. They will then be followed up for the study at 10 weeks with repeat measures of CPAP compliance, daytime sleepiness and quality of life indices to look for any measurable changes.
Patients will be selected from a cohort of CPAP users who are followed up at Papworth hospital.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
CPAP compliance (measured as average CPAP use in hours per night)

Key secondary outcome(s))
1. Improvement in generic quality of life index - Short form 36 (SF-36)
2. Improvement in sleep apnoea quality of life index (SAQLI)
3. Epworth sleepiness scale score (ESS)
4. Side effects
5. Comfort level
6. Patient preference for different device
7. Changes in objective measure of excessive daytime sleepiness (OSLER test)

Completion date
30/04/2010

Eligibility

Key inclusion criteria
1. Diagnosed OSA (AHI greater than 4 per hour)
2. On CPAP for at least 6 weeks with average use less than 4 hours per night
3. Intolerant of CPAP despite ensuring pressure minimised to least effective, mask fit and humidification reviewed as appropriate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

1. Refuse informed consent or unable to give consent.
2. AHI less than 5 per hour off CPAP.
3. Moderate to severe airflow obstruction (Forced Expiratory Volume in 1 second [FEV1] / Forced Vital Capacity Percentage [FVC%] less than 60%).
4. Central sleep apnoea (central events more than 50% of all the apnoeas / hypopnoeas).
5. Decompensated congestive heart failure on clinical examination.
6. Hypercapnia ($PaCO_2$ >6.5 KPa).
7. Previous exposure to Bi–level positive airway pressure support.

Date of first enrolment
01/04/2009

Date of final enrolment
30/04/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Papworth Hospital NHS Trust
Papworth Everard
United Kingdom
CB23 3RE

Sponsor information

Organisation
Papworth Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/01qbebb31

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Papworth Hospital NHS Foundation Trust (UK) - (Local R& D ref: PO1349)

Funder Name
B and D electromedicals (UK) - limited funding

Results and Publications

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	01/06/2015		Yes	No