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Long-term comparison of BiPAP® autoSV™ versus continuous positive airway pressure in patients with mixed sleep apnoea syndrome and underlying cardiovascular diseases (Vergleich der behandlung mit kontinuierlicher konstanter psotivdruckatmung [CPAP] und der beatmung mit adaptiver servovventilation mit dem gerat BiPAP® autoSV™ bei patienten mit cheyne-stokes-atmung)

Submission date 16/04/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 16/05/2007	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 11/12/2012	**Condition category** Circulatory System	[_] Individual participant data

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
Rand001

Study information

Scientific Title

Study objectives
BiPAP® autoSV™ is superior to Continuous Positive Airway Pressure (CPAP) in reducing breathing disturbances during sleep and improving cardiac function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the local ethics committee (Universitat Witten/Herdecke Ethik-Kommission) on the 4th September 2006.

Study design
Randomised controlled double blind trial of BiPAP® autoSV™ therapy versus CPAP

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Sleep disordered breathing and cardiovascular disease.

Interventions
Control:
Nasal Continuous Positive Airway Pressure (CPAP) is the current gold standard treatment for

Obstructive Sleep Apnoea Syndrome. CPAP can crudely be described as a small air pump attached to a mask that is worn over the nose and pumps a fixed amount of pressurised air through the nares to prevent upper airway collapse whilst sleeping.

Intervention:
Adaptive Servo-Ventilation machines (ASV) provide Expiratory Positive Airway Pressure (EPAP) or CPAP support to sustain upper-airway patency as with a CPAP machine but also modulate the Inspiratory Positive Airway Pressure (IPAP) in response to central and cheyne-stokes events.

After a baseline polysomnography (first night) patients are randomly assigned to either CPAP or BiPAP® autoSV™. They will then undergo two titration nights on therapy. After the first titration night the patients are asked for side-effects using a standardised questionnaire. On the fourth night the titrated values are validated. The CPAP level should be set to greater than or equal to 10 mbar.

After 3 months and 12 months the patients are re-evaluated polysomographically and have outcomes measured. The devices are also read out for treatment compliance. After six months and nine months the patients are contacted by telephone to find out any problems with mask, device or compliance.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Central AHI, measured at baseline, 3 and 12 months.

Secondary outcome measures
1. Total AHI, measured at baseline, 3 and 12 months
2. Maximal oxygen uptake (VO2 max), measured at baseline, 3 and 12 months
3. Left ventricular ejection fraction (echocardiography), measured at baseline, 3 and 12 months
4. Minimal and mean oxygen saturation (polysomnography), measured at baseline, 3 and 12 months
5. Compliance, measured at 3 and 12 months only
6. Quality of life (Minnesota questionnaire), measured at baseline, 3 and 12 months
7. Brain Natriuretic Peptide (BNP) level, measured at baseline, 3 and 12 months
8. Mortality, measured at 3 and 12 months only
9. Rate of cardiovascular complications, for example hospital admissions are examined for twelve months, measured at 3 and 12 months only

Overall study start date
01/01/2007

Completion date
01/07/2008

Eligibility

Key inclusion criteria

1. Men and women 18 years of age and older
2. Arterial hypertension, ischaemic heart disease, idiopathic dilated cardiomyopathy with heart failure functional class New York Heart Association (NYHA) II and III and left ventricular ejection fraction greater than 20% (echocardiography)
3. Mixed sleep apnoea syndrome with an Apnoea Hypopnoea Index (AHI) greater than or equal to 15/hour with a proportion of central/periodic disturbances of less than 80% and a proportion of obstructive disturbances of between 20 and 50%
4. Medical treatment of their underlying heart disease has been optimised

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
70

Key exclusion criteria
1. Heart failure functional class NYHA IV
2. Myocardial infarction, unstable angina or cardiac surgery within the previous three months, obstructive disturbances of 50% or greater
3. Pregnancy
4. Patients with pure Cheyne-Stokes Respiration (CSR)/Central Sleep Apnoea (CSA) (greater than 80% of disturbances), patients with greater than 50% obstructive disturbances

Date of first enrolment
01/01/2007

Date of final enrolment
01/07/2008

Locations

Countries of recruitment
Germany

Study participating centre
Wissenschaftliches Institut Bethanien e.V.
Solingen
Germany
42699

Sponsor information

Organisation
Respironics International, Inc (France)

Sponsor details
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92565

Sponsor type
Industry

Website
http://www.respironics.com

ROR
https://ror.org/05jz46060

Funder(s)

Funder type
Industry

Funder Name
Respironics International, Inc (France)

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	01/08/2012		Yes	No