

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 positivdruckatmung [CPAP] und der beatmung mit adaptiver servoventilation 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 ☒ 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

Contact name
Prof Winfried Randerath

Contact details
Wissenschaftliches Institut Bethanien e.V.
Aufderhoherstrasse 169
Solingen
Germany
42699

Additional identifiers

Protocol serial number

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.

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

Central AHI, measured at baseline, 3 and 12 months.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

ROR

<https://ror.org/05jz46060>

Funder(s)**Funder type**

Industry

Funder Name

Respironics International, Inc (France)

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	01/08/2012		Yes	No