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Evaluate the effectiveness of servo-ventilation therapy in patients with co-existing sleep related breathing disorders and heart failure [Evaluation de la BiPAP autoSV Advanced dans le traitement du syndrome dapnées mixtes du sommeil chez les patients ayant une insuffisance cardiaque congestive]

Submission date 08/04/2010	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 22/04/2010	**Overall study status** Stopped	
Last Edited 01/03/2011	**Condition category** Nervous System Diseases	

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
EAME09ASV01

Study information

Scientific Title
Evaluate the effectiveness of servo-ventilation therapy in patients with co-existing sleep related breathing disorders and heart failure: a 6-month longitudinal case-control observational study

Study objectives
Servo-ventilation therapy may improve the quality of life and prognosis in patients with co-existing sleep disordered breathing and heart failure. This is an observational trial where we would like to follow up a group of such patients and to evaluate the outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comité de Protection des Personnes Sud Est V approved on the 13th May 2009 (ref: CPP 09-RESP-1)

Study design
Observational longitudinal case-control multicentre study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Sleep related breathing disorders/heart failure

Interventions

After checking inclusion/exclusion criterias and having the patient consent signed, the following steps will be as follows:

1. First Visit (V0):
1.1. Polysomnography (PSG) diagnostic night
1.2. Clinical evaluation
1.3. Arterial and blood review
1.4. Cardiac evaluation
1.5. PSG control night

2. Second Visit at 10 days (V1):
2.1. Clinical evaluation
2.2. Blood pressure measurement
2.3. Questionnaires
2.4. Device compliance download
2.5. Polygraphy ambulatory recording

3. Third Visit at 1 month (V2):
3.1. Clinical evaluation
3.2. Blood pressure measurement
3.3. Questionnaires
3.4. Device compliance download

4. Fourth Visit at 3 months (V3):
4.1. Clinical evaluation
4.2. Blood pressure measurement
4.3. Questionnaires
4.4. Device compliance download
4.5. Effort test
4.6. Walking test
4.7. Blood gases/NTProBNP

5. Fifth Visit at 6 months (V4):
5.1. Clinical evaluation
5.2. Blood pressure measurement
5.3. Questionnaires
5.4. Device compliance download
5.5. Scan or isotope imaging
5.6. Effort test
5.7. Measuring the ventilatory response to CO2
5.8. Walking test
5.9. Blood gases/determination of NT-proBNP
5.10. PSG control night

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Assess the correction of the apnoea/hypopnoea index (AHI); the method to evaluate this outcome will be the PSG recording.

Secondary outcome measures
1. Cardiovascular function: assessing long-term changes in left ventricular ejection fraction (LVEF) when using the in BiPAP autoSV Advanced:
1.1. LVEF: assessed by measuring Scan or Isotope imaging
1.2. Left Ventricular Diastolic Function (FDVG)
1.3. Determination of NT-proBNP

2. Improvement of cardiorespiratory function in BiPAP autoSV Advanced:
2.1. Effort Test: measurement of oxygen consumption (VO2max), ventilatory threshold value, ventilatory response to CO2 (VE/VCO2)
2.2. Six-minute walk Test: to assess the distance in meters, heart rate and SaO2 at the end of trial
2.3. PSG: blood average oxygen Saturation (SaO2) and oxygen desaturation index per hour of sleep. The desaturation threshold is set at 3%. In addition, we calculate the time spent with SaO2 <90%

3. Quality of sleep:
3.1. Total time of sleep (in minutes)
3.2. Percentage of REM sleep, slow wave sleep light (I and II), and slow deep (III and IV)
3.3. Index of arousal associated with respiratory events per hour

4. Effectiveness of sleep: ratio of total sleep time and time spent in bed

5. Questionnaires:
5.1. Daytime sleepiness: Epworth Sleepiness Questionnaire (QSE)
5.2. Quality of life Questionnaire Minnesota

6. Acceptance rate expressed by:
6.1. Compliance of more than 4 hours
6.2. Percentage of patients continuing their treatment at 6 months

Overall study start date
10/04/2010

Completion date
10/04/2011

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Patients with heart failure and obstructive/central sleep apnoea (no specific age range or sex)
2. Naive patients to positive airway pressure therapy
3. Apnoea/Hypopnoea Index greater than 30/h with at least 30% of central events
4. Left ventricular ejection fraction less than 45%

5. Patients with a New York Heart Association (NYHA) class between II and IV
6. Stable and optimised medical cardiac therapy since one month at least
7. Informed consent signed

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Patients with associated chronic obstructive pulmonary disease
2. Patients with unstable heart failure or stable since less than one month
3. Patients with unstable angina pectoris or stable since less than one month
4. Patients with stroke
5. Patients with ischaemic cardiomyopathy or cardiogenic oedema
6. Patients with a cardiac resynchronisation scheduled within the next 6 months
7. Patients with a valvular surgery scheduled within the next 6 months
8. Patients participating to another clinical trial or not affiliated to the social security system
9. Patients in jail or hospitalised without consent
10. Majors protected by the law or detainees
11. Minors
12. Pregnant or nursing women

Date of first enrolment
10/04/2010

Date of final enrolment
10/04/2011

Locations

Countries of recruitment
France

Study participating centre
Pôle de Rééducation et Physiologie
Grenoble
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38043

Sponsor information

Organisation
Phillips Respironics International Inc. (France)

Sponsor details
2 rue du château de Bel Air
Carquefou
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44470

Sponsor type
Industry

Website
http://www.medical.philips.com/main/homehealth/index.wpd

ROR
https://ror.org/05jz46060

Funder(s)

Funder type
Industry

Funder Name
Phillips 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