

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 d'apnées mixtes du sommeil chez les patients ayant une insuffisance cardiaque congestive]

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| Submission date 08/04/2010 | Recruitment status Stopped | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 22/04/2010 | Overall study status Stopped | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 01/03/2011 | Condition category Nervous System Diseases | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

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

France

38043

Sponsor information

Organisation

Phillips Respironics International Inc. (France)

Sponsor details

2 rue du château de Bel Air
Carquefou
France
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