ISRCTN04353156 https://doi.org/10.1186/ISRCTN04353156

Randomised controlled trial of BiPAP autoSV™ therapy in patients with chronic heart failure and sleep-disordered breathing

Submission date
26/04/2007

Recruitment status
No longer recruiting

Registration date
16/05/2007

Overall study status
Completed

Last Edited
26/06/2014

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Michael Pfeifer

Contact details
Klinik und Poliklinik fűr Innere Medizin II
University of Regensburg
Franz-Josef-Strauß-Allee 11
Regensburg
Germany
93042 Regensburg

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RI-SDBHF-2006-02

Study information

Scientific Title

Study objectives
The application of BiPAP autoSV™ to patients with Heart Failure (HF) and Sleep Disordered Breathing (SDB) will:
1. Improve daytime left ventricular ejection fraction
2. Improve exercise capacity, daytime activity, daily symptoms of HF and SDB and oxygen saturation
3. Decrease both the central and obstructive component of the Apnoea-Hypopnoea Index (AHI), B-type natriuretic peptide levels and ventilation during exercise

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study has been approved by the ethics committees of all four sites:
1. Germany (Universty of Regensburg) - Protocol approved by the Ethikkommission an der Universitat Regensburg on 12th April 2007 (ref: 07/011)
2. UK (Prince Phillip Hospital) - Protocol approved by Dyfed Powys Local Research Ethics Committee on 2nd January 2007 (ref: 06/WMW01/57)
3. France (Clamart Hospital) - Protocol approved by the Comite de Protection des Personnes Il-de-France VII on 14th March 2007 (ref: 2007-A00014-49)
4. Canada (Hopital laval) - Protocol approved by the Comite d'ethique de la recherce de l'Hopital Laval on 11th April 2007 (ref: 20157)

Study design
Randomised parallel open-label trial with blinded evaluation of outcomes

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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
Heart failure with sleep disordered breathing

Interventions
This is a randomised parallel, open-label trial with blinded evaluation of outcomes involving four centres of 12 weeks BiPAP autoSV™ and optimal medical management versus optimal medical management alone. The BiPAP autoSV™ is intended to augment breathing by supplying pressurised air through a patient circuit. It senses the patients breathing effort by monitoring airflow in the patient circuit and adjusts its output to assist in inspiration and expiration. This assistance is provided by the administration of two levels of positive pressure. During expiration, pressure is variable positive or near ambient. During inspiration, pressure is variable positive and always higher than the expiratory level.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Left ventricular ejection fraction, measured at baseline and three months.

Secondary outcome measures
1. Six-minute walk test
2. Borg Scale
3. Minnesota Living with Heart Failure Questionnaire (MLHFQ)
4. Functional Outcomes of Sleep Questionnaire (FOSQ)
5. 36-item Short Form health survey (SF-36)
6. Fatigue severity scale
7. Epworth sleepiness scale
8. The Apnoea-Hypopnoea Index (AHI)
9. Obstructive AHI
10. Central AHI
11. Mean oxygen saturation
12. Daytime activity
13. Glomerular filtration rate
14. B-type natriuretic peptide cardiopulmonary exercise test

All secondary outcomes measured at baseline and three months.

Overall study start date
21/04/2007

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. HF due to ischaemic, non-ischaemic or hypertensive cardiomyopathy diagnosed by a cardiologist
2. Aged 18 to 80 years
3. Impaired exercise capacity (New York Heart Association [NYHA] class II or III)

4. Objectively impaired left ventricular ejection fraction less than 40%, assessed by echocardiography
5. Stable clinical status and stable optimal medical therapy according to the guidelines of the European Society of Cardiology for at least four weeks
6. An AHI greater than or equal to 20 per hour of sleep assessed by in-laboratory polysomnography
7. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Not Specified

Target number of participants
70

Key exclusion criteria
1. Unstable angina, myocardial infarction, cardiac surgery or hospital admissions within the previous three months
2. NYHA class I or IV
3. Pregnancy
4. Contraindications for BiPAP autoSV™:
a. mean supine Blood Pressure [BP] less than 60 mmHg
b. inability to clear secretions
c. patients at risk for aspiration of gastric contents
d. history of pneumothorax and/or pneumomediastinum
e. a history of epistaxis
f. causing pulmonary aspiration of blood
5. Patients on or with indication for oxygen therapy
6. Severe restrictive and obstructive airways disease
7. HF due to primary valve disease
8. Awaiting heart transplant
9. Inability or unwillingness to provide written informed consent
10. Diurnal symptoms of SDB requiring immediate treatment

Date of first enrolment
21/04/2007

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Canada

France

Germany

United Kingdom

Study participating centre
Klinik und Poliklinik fűr Innere Medizin II
Regensburg
Germany
93042 Regensburg

Sponsor information

Organisation
Respironics Inc. (USA)

Sponsor details
286 Site
1740 Golden Mile Highway
Monroeville
United States of America
PA 15146-2094

Sponsor type
Industry

Website
http://www.respironics.com/

ROR
https://ror.org/03kw6wr76

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	01/11/2013		Yes	No