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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li><li>Protocol</li></ul>		
26/04/2007				
Registration date	Overall study status	Statistical analysis plan		
16/05/2007	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
26/06/2014	Circulatory System			

# 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

Protocol serial number

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 Ilde-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

# Study type(s)

**Treatment** 

# 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(s)

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

#### Key secondary outcome(s))

- 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.

#### 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

## Healthy volunteers allowed

No

# Age group

Adult

#### Lower age limit

18 years

#### Upper age limit

80 years

#### Sex

**Not Specified** 

#### 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

**United Kingdom** 

Canada

France

Germany

Study participating centre Klinik und Poliklinik für Innere Medizin II Regensburg

Germany

93042 Regensburg

# Sponsor information

## Organisation

Respironics Inc. (USA)

#### **ROR**

https://ror.org/03kw6wr76

# 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	01/11/2013	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes