BiPAP Auto with BiFlex® as a rescue therapy for optimally treated obstructive sleep apnoea patients who demonstrate poor compliance to continuous positive airway pressure therapy

Submission date 05/11/2008	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 11/12/2008	Overall study status Completed	 Statistical analysis plan Results
Last Edited 14/11/2013	Condition category Nervous System Diseases	Individual participant dataRecord updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers EAME06AUTOBILEVEL01

Study information

Scientific Title

Acronym AUTOBILEVEL

Study objectives

BiPAP Auto with Bi-Flex® therapy will improve compliance, subjective sleepiness and quality of life in obstructive sleep apnoea patients who demonstrate poor compliance to standard fixed pressure therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee for Protection of Human Subjects in Biomedical Research (CCPPRB), Lille, 02 /05/2006, ref: CP 06/57

Study design

Observational study

Primary study design Observational

Secondary study design Other

Study setting(s) Other

Study type(s) Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Obstructive sleep apnoea

Interventions

After a full polysomnography (PSG) patients will be given a BiPAP Auto with Bi-Flex® device. Patients will be followed up at 15 days and 10 weeks.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

To determine whether rescuing optimally treated OSA patients who demonstrate poor compliance to PAP therapy by transitioning them onto BiPAP Auto with Bi-Flex improves compliance, subjective sleepiness and quality of life.

1. Compliance will be measured at 15 days and 10 weeks by retrieving device data

2. Subjective compliance and quality of life will be measured by Epworth Sleepiness Questionnaire and Functional Outcomes of Sleep Therapy questionnaire at baseline, 15 days and 10 weeks

Secondary outcome measures

1. Determination of comfort between BiPAP Auto with Bi-Flex® and previous device used. Measured by Device Comfort scale at baseline, 15 days and 10 weeks.

2. Identify barriers to successful transition onto BiPAP Auto with Bi-Flex®. Patients' previous machine type and mask will be noted and effect on transition assessed.

3. To determine the machine types used by patients who demonstrate poor compliance to fixed PAP therapy and their treatment efficacy during sleep. Previous machine type will be noted at baseline and treatment efficiency during baseline PSG.

Tertiary objective:

4. To investigate the level of agreement between Apnoea-Hypopnea Index (AHI) measured at Visit 1 (15 days) by PSG and an autotitrating PAP device in a subgroup of patients. Carried out at Visit 1 by PSG.

Overall study start date

21/08/2006

Completion date

26/02/2008

Eligibility

Key inclusion criteria

 Male and female patients 18+
 Compliance to positive airway pressure (PAP) below the minimally acceptable level of 4 hours use on >=70% of nights over the past 4 weeks
 Ability to provide written informed consent

Participant type(s) Patient

Age group Adult

Lower age limit 18 Years **Sex** Both

Target number of participants 30

Key exclusion criteria

Wrong mask choice
 Wrong mask size
 Nasal congestion
 Other symptoms requiring humidification

Date of first enrolment 21/08/2006

Date of final enrolment 26/02/2008

Locations

Countries of recruitment France

Study participating centre Laboratoire du Sommeil Lille France 59800

Sponsor information

Organisation Respironics International Inc. (France)

Sponsor details 20 Rue-Jacques Daguerre Rueil-Malmaison Paris France 92500 steven.coughlin@respironics.com

Sponsor type Industry Website http://www.respironics.com

ROR https://ror.org/05jz46060

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