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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

Registration date
11/12/2008

Overall study status
Completed

Last Edited
14/11/2013

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
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
1. Male and female patients 18+
2. Compliance to positive airway pressure (PAP) below the minimally acceptable level of 4 hours use on >=70% of nights over the past 4 weeks
3. 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
1. Wrong mask choice
2. Wrong mask size
3. Nasal congestion
4. 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
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Sponsor information

Organisation
Respironics International Inc. (France)

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Sponsor type
Industry

Website
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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