

Therapy efficacy, compliance and long-term outcome of Auto-bilevel therapy compared to continuous positive airway pressure (CPAP) therapy in obstructive sleep apnoea (OSA) patients

Submission date 29/10/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 11/12/2008	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 20/11/2012	Condition category Nervous System Diseases	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
EAME05AUTOBILEVEL01

Study information

Scientific Title

Acronym

AUTOBILEVEL

Study objectives

We hypothesised that auto-bilevel therapy would be equivalent to fixed continuous positive airway pressure (CPAP) therapy on parameters of objective and subjective compliance and therapeutic effectiveness in patients with moderate to severe obstructive sleep apnoea.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethikkommission of Charite Campus-Mitte gave approval on the 1st March 2006 (ref: EA1/044/08)

Study design

Controlled, double-blind randomised study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Obstructive sleep apnoea

Interventions

After a CPAP titration night patients will be randomised to three months of either BiPAP auto with Biflex or fixed level CPAP. Patients will be followed up at 1, 4, 8 and 12 weeks.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Treatment and therapeutic efficacy will be measured by polysomnography (PSG) at diagnosis, titration and 12 weeks (end of study).

Key secondary outcome(s)

1. Objective compliance measured by device memory download at one week and the end of the study
2. Subjective compliance and parameters of wellbeing measured at baseline, 4, 8, 12 weeks

3. Epworth Sleepiness Scale measured at baseline (after diagnostic PSG and after titration PSG), 4, 8 and 12 weeks
4. Pittsburgh Sleep Quality Index measured at baseline (after diagnostic PSG only), 4, 8 and 12 weeks
5. Functional Outcomes of Sleep Questionnaire measured at baseline (after diagnostic PSG only), 4, 8 and 12 weeks
6. Calgary Sleep Apnoea Quality of Life Index measured at baseline (after diagnostic PSG only), 4, 8 and 12 weeks
7. 12-item Short Form (SF-12) measured at baseline (after diagnostic PSG only), 4, 8 and 12 weeks
8. Visual Analogue Scale measured in the morning and evening at baseline (after diagnostic PSG and after titration PSG), 4, 8 and 12 weeks
9. Treatment Satisfaction Visual Analogue Scale measured at baseline (after titration PSG only), 4, 8 and 12 weeks
10. Treatment Comfort Visual Analogue Scale measured at baseline (after titration PSG only), 4, 8 and 12 weeks
11. Mask/Interface Comfort Visual Analogue Scale measured at baseline (after titration PSG only), 4, 8 and 12 weeks

Completion date

09/06/2007

Eligibility

Key inclusion criteria

1. Apnoea/Hypopnoea Index (AHI) greater than 15/h
2. Aged greater than or equal to 21 years and less than or equal to 65 years, either sex
3. Body mass index (BMI) less than 40 kg/m²
4. Able to follow the study protocol
5. Successful CPAP titration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Drug abuse
2. Intake of central relevant drugs, sedatives, or other drugs with impairment of sleep
3. Alcohol abuse; consume more than 30 g/d
4. Participation in other clinical-pharmacological studies up to 4 weeks prior of study begin
5. Psychiatric or neurological diseases resulting in impairment of sleep, therapy or compliance
6. Thyroidal dysfunction
7. Chronic pain syndromes
8. Acute cardiac, pulmonary, and other internal diseases

9. Chronic cardiac, pulmonary and other internal diseases resulting in impairment of sleep
10. Central sleep-related breathing disorders or other disorders resulting in hypoventilation
11. Periodic leg movements (PLM)/restless legs syndrome (RLS)
12. Previous exposure to either CPAP or bilevel therapy

Date of first enrolment

05/06/2006

Date of final enrolment

09/06/2007

Locations

Countries of recruitment

Germany

Study participating centre

Center of Sleep Medicine

Berlin

Germany

10117

Sponsor information

Organisation

Respironics International, Inc. (France)

ROR

<https://ror.org/05jz46060>

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	01/09/2012		Yes	No