Therapy-efficacy of automatic positive airways pressure therapy with A-Flex compared to standard automatic positive airways pressure therapy in obstructive sleep apnoea (OSA) patients

Submission date	Recruitment status	Prospectively registered
18/04/2008	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
15/05/2008	Completed	Results
Last Edited	Condition category	Individual participant data
15/05/2008	Nervous System Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number EAME07AFLEX01/02

Study information

Scientific Title

Acronym

A-Flex Validation

Study objectives

A-Flex is as effective as automatic positive airways pressure (APAP) in reducing respiratory events and arousals in patients with obstructive sleep apnoea (OSA).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

- 1. France: Ethics of Lille on the 11th February 2008
- 2. Germany: Charite Ethikkommission, Mitte Campus on the 30th July 2008

Study design

Randomised, controlled, double-blind, cross-over study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Obstructive sleep apnoea

Interventions

A-Flex: automatic positive airways pressure device featuring pressure relief technology APAP: standard automatic positive airways pressure device

The duration of treatment and follow up during the fixed follow-up period will be three months in both arms.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

A-Flex is as effective as APAP in reducing respiratory events and arousals in patients with OSA, measured with the Apnoea-Hypopnea Index at baseline.

Key secondary outcome(s))

- 1. A-Flex is more comfortable than APAP, measured using the Visual Analogue Scale [VAS] at baseline
- 2. Compliance (internal clock within the device) is higher on A-Flex compared to APAP, measured at one and three months
- 3. Subjective daytime sleepiness is improved on A-Flex compared to APAP, measured using the Epworth Sleepiness Scale at baseline, one and three months
- 4. Quality of life is improved on A-Flex compared to APAP, measured using the Functional Outcomes of Sleep Questionnaire at baseline, one and three months

Completion date

30/09/2008

Eligibility

Key inclusion criteria

- 1. Apnoea-Hypopnoea Index (AHI) greater than 15/h confirmed by full polysomnograph (PSG)
- 2. Aged greater than or equal to 21 to less than or equal to 65 years, either sex
- 3. Body mass index (BMI) less than 40 kg/m^2
- 4. Able to follow the study protocol

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Acute upper respiratory infection, encephalitis, sinusitis or middle ear infection
- 2. Drug abuse
- 3. Intake of central relevant drugs, sedatives, or other drugs which impair sleep
- 4. Alcohol abuse
- 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 continuous positive airways pressure (CPAP) or bi-level therapy
- 13. Patients experiencing acute dermatitis or other skin lesions or trauma interfering with the application of a mask
- 14. Participation in another clinical study in the past four weeks

Date of first enrolment

01/08/2007

Date of final enrolment

30/09/2008

Locations

Countries of recruitment

France

Germany

Study participating centre Charité-Universitätsmedizin Berlin 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?

Participant information sheet 11/11/2025 No Yes