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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/08/2007

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

Age group
Adult

Sex
Both

Target number of participants

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)

Sponsor details
20 Rue Hacques Daguerre
Rueil-Malmaison

Paris
France
92500

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