Evaluation of the System One RemStar Auto A-Flex for the Treatment of OSA

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Compare the performance of the Philips Respironics Sleep Therapy Auto System to a fixed CPAP device for the treatment of OSA and validate its event detection capabilities.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON36812

Source
ToetsingOnline

Brief title
Encore EAME09PRSTS01

Condition

- Other condition
- Respiratory disorders NEC

Synonym
brief interruptions of breathing during sleep, Obstructive Sleep Apnoea

Health condition

Sleep disorder

Research involving
Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: Respironics International

Intervention

Keyword: Automatic PAP (APAP), Continuous Positive Airway Pressure (CPAP), Obstructive Sleep Apnoea (OSA)

Outcome measures

Primary outcome

Automatic Positive Airway Pressure (APAP) delivered throughout the night by the

Philips Respironics Sleep Therapy Auto System, in subjects with OSA, will

reduce the following variables to a similar level to fixed Continuous Positive

Airway Pressure (CPAP) delivered by the same device.

1. Apnoea-hypopnoea index

Secondary outcome

Automatic Positive Airway Pressure (APAP) delivered throughout the night by the

Philips Respironics Sleep Therapy Auto System, to subjects with OSA, will alter

the following variables to a similar level to fixed Continuous Positive Airway

Pressure (CPAP) delivered by the same device.

2. SpO2 - Nocturnal oxygenation

i. Total time spent <90%

ii. Lowest SpO2 during the night

iii. Average SpO2 during the night

3. TST - Total sleep time

4. SE% Sleep efficiency

5. Sleep Architecture:

a. Min / % Non-REM sleep

i. Min / % N1

ii. Min / % N2

iii. Min / % N3

b. Min / % REM sleep

c. Min / % Wake After Sleep Onset (WASO)

d. Arousals

i. # of arousals / awakenings (all cause)

ii. Arousals due to PLMS

iii. Arousal Index (AI)

iv. Arousals due to Respiratory Disturbance (RDI)

6. Average Pressure Outputs

7. 90% Pressure Outputs

The breathing event output (total and by epoch) from the Philips Respironics Sleep Therapy Auto System will result in a number of events (clear airway apnoea, obstructed airway apnoea, hypopnoea, apnoea hypopnoea index, respiratory effort related arousals and Cheyne Stokes Respiration) that is in agreement with those obtained from a full clinical PSG.

Study description

Background summary

Obstructive Sleep Apnoea
Obstructive Sleep Apnoea (OSA) is the most common form of sleep-disordered breathing (SDB), affecting approximately 2% of women and 4% of men (1). It is generally characterised by persistent loud snoring and repetitive partial (hypopnoea) and full (apnoea) collapse of the upper airway during sleep. Each collapse of the upper airway lasts for at least 10 seconds and is terminated by an arousal response leading to broken sleep and excessive daytime sleepiness. OSA severity is commonly assessed by using the Apnoea/Hypopnoea Index (AHI) which indicates the number of upper airway events that occur per hour of sleep. The majority of European physicians would describe obstructive sleep apnoea as being clinically significant if the patient*s AHI was >= 15 with symptoms such as snoring and excessive daytime sleepiness.

Untreated OSA increases the risk of falling asleep while doing routine tasks resulting in an increased incidence of workplace accidents (2) and motor vehicle collisions while driving (3;4). OSA can also reduce quality of life (5) and increase the risks of developing other long term health risks such as stroke (6), heart rhythm abnormalities (7), high blood pressure (8) and type 2 diabetes (9).

Polysomnography
Polysomnography (PSG) with electroencephalographic sleep staging, oximetry and respiratory monitoring is the *gold standard* for the diagnosis of SDB and to conduct a CPAP titration. Polysomnography refers to the collective process of monitoring and recording physiologic data related to sleep and wakefulness plus respiration.

Continuous Positive Airways Pressure Therapy
Continuous Positive Airway Pressure (CPAP) is the first-line medical therapy for treatment of OSA, with multiple studies documenting its effectiveness in decreasing the associated morbidity and mortality of Obstructive Sleep Disordered Breathing. This therapy is very effective in reducing the frequency and number of apnoeas and hypopnoeas, improving sleep quality as well as the symptoms of daytime sleepiness. CPAP prevents partial and complete airway obstruction by stabilising the upper airway, acting as a pneumatic splint to maintain UA patency during sleep. A blower unit produces controlled positive-pressure airflow that is introduced through the nasal passage, holding the soft tissue of the uvula and soft palate and the soft pharyngeal tissue in the upper airway in position so the airway remains open. Typically, CPAP is applied via a patient interface such as a nasal mask, oronasal mask or nasal pillows.

With proper patient compliance, CPAP therapy can effectively eliminate sleep disordered breathing (SDB)/OSA in addition to improving daytime hypersomnolence

and alertness, and improve the overall quality of the patient*s life. Patients who are not able to comply with CPAP therapy may be offered Bi-Level therapy, an alternative mode of treatment to improve compliance with positive airway pressure therapy.

Continuous Positive Airways Pressure Titration

The goal of polysomnography testing and titration in a sleep lab is to identify an effective pressure that will prevent apnoea, hypopnoea, snoring and respiratory effort - related arousals in all body positions and sleep stages. Attended sleep studies allow the technician to adjust the pressure to meet changes in body position and sleep stage and to intervene for mask leaks or persistent hypoxemia after airway patency is restored.

There are disadvantages to performing CPAP titration in the sleep lab using full polysomnography as this technique is labour intensive and can lead to long scheduling delays. Some patients, especially those in rural areas, may not have easy access to a standard sleep lab. For other patients, an optimal pressure effective in all situations cannot be identified in a single study night. Auto-titrating CPAP devices, which vary the delivered pressure during the night in response to periods of apnoea and hypopnoea during sleep, are an alternative means of finding the optimal pressure levels required for treatment.

These devices are designed to increase pressure as needed to maintain airway patency and then to decrease pressure if no event is detected over a set period of time. Because the minimum effective pressure is delivered (auto adjusting), the mean pressure is often lower than the optimal fixed CPAP pressure (10). This lower pressure could increase acceptance and adherence with chronic positive pressure treatment. Most automatic PAP (APAP) units have the ability to store pressure vs. time data and many can also record leak, apnoea and hypopnoea information. This information can be transferred to a computer and analysed quickly to provide both summary information and more detailed pressure and leak versus time plots on selected nights. A maximum pressure or a pressure thought satisfactory for the majority of the time as the optimal effective CPAP level for chronic treatment could then be chosen. This effective pressure level (Peff) of CPAP for a given individual varies in relation to a number of factors: ingestion of alcohol and other sedative drugs, body position while sleeping, sleep stages, and even the course of CPAP itself, which may result in decrease of (Peff) itself (11).

Continuous Positive Airways Pressure Intolerance

Clinical effectiveness of CPAP therapy requires nightly use. Resistance to and intolerance of CPAP poses a serious limitation to its use. Failure to comply with treatment has been reported to be high, with approximately 25% of patients completely abandoning therapy during the first year treatment (12). Most problems associated with nasal CPAP relate to issues of rhinitis, nasal congestion, mask discomfort, claustrophobia and difficulty adjusting to the pressure, especially during expiration (10).. Regardless of actual improvement in the apnoea/hypopnoea index (AHI), it is the patient*s perception of their

improvement that increases compliance. If the patient feels that CPAP is beneficial for them they are understandably more likely to comply with the treatment. Those patients who are most compliant seem to be the most symptomatic and have a greater awareness of the beneficial effects of CPAP. Under these conditions, patients seem to use CPAP for the optimal length of time, regardless of the side effects linked to the treatment (11).

Preliminary Clinical Data
A number of small studies were performed during the development of Philips Respironics new Sleep Therapy Platform that are relevant to the APAP device that will be investigated in this study. First, a user preference validation trial including 284 existing CPAP patients were transitioned onto Philips Respironics new Sleep Therapy Platform (55 used the APAP device) and demonstrated that 79% of the surveyed subjects rated the new device as equivalent or superior on noise, cleaning, usability, ease of transport, and overall preference to their current device.

Preliminary comparisons of the new auto algorithm were made with the previous auto algorithm (M-Series, Philips Respironics) in a 20 subject study in which patients were randomised to receive each algorithm on consecutive nights with full PSG recordings. Data from 16 completed subjects showed no statistically significant difference between the new and previous algorithm for all sleep variables.

Device Mean SD p-value
New auto algorithm AHI 2.9 ±3.4 0.079
Previous auto algorithm AHI 3.2 ± 3.4
New auto algorithm 90% PP 10.4 ± 2.3
0.422
New auto algorithm 90% PP 10.8 ± 3.3

Furthermore, when comparing the advanced event detection capabilities of the new auto algorithm to similar manually scored events on consecutively measured PSGs, a strong significant correlation between the algorithm derived Obstructed Apnoea Index, Clear Apnoea Index and PSG scored events was demonstrated.

Finally an in lab comparison was performed of the obstructed and clear apnoea detection capabilities of the new auto algorithm. Nineteen participants with Sleep Disordered Breathing were studied overnight with full PSG. Scored PSG Obstructive and central apnoeas identified using standard criteria were compared to obstructed airway and closed airway apnoeas identified by the new auto algorithm. The Obstructed Apnoea Indices showed an intra-class correlation coefficient of 0.976, and the Central / Clear Apnoea Indices showed an intra-class correlation coefficient of 0.728. The algorithm-detected Clear Apnoea Indices were also compared to *specialised scoring* Clear Apnoea Indices on the PSG (where the scorer had been trained to consider the effect of the pressure pulses when classifying events), with an intra-class correlation

coefficient of 0.968.

Justification for the Study
In addition to the clinically-proven auto-titrating algorithm inherited from the our previous auto device, Philips Respironics new Sleep Therapy System also has the ability to distinguish obstructed and clear airway apnoea, and detect RERA and Cheyne-Stokes respiration. The successful detection of these events is integral to the efficacy of the auto algorithm and accordingly the ability of the new auto algorithm to effectively treat patients with OSA. Thus, the ability of this new system to reliably detect these events needs to be evaluated in an adequately powered study.

Study objective

Compare the performance of the Philips Respironics Sleep Therapy Auto System to a fixed CPAP device for the treatment of OSA and validate its event detection capabilities.

Study design

Double blind, randomised, crossover study.

Before signing the consent form for this study, the details of the subjects* participation will be fully explained to them. Subjects will be instructed that they will be trialling a positive airways pressure device with two different modes, without being given any further information about the modes. The PSG technician will alter machine setting using PC Direct software with the screen turned away from the patient.

Following the standard education and acclimatisation program of the centre, in which subjects will undergo a daytime CPAP session at a constant pressure of 4 cm H2O using several different interface models so that an appropriate interface can be selected, eligible subjects will complete a CPAP titration study with full PSG monitoring. CPAP shall start with a value of 4cmH2O and be increased in 1cmH2O increments to the point where disordered breathing, including hypopnoeas, RERAs, snoring, and flow limitations, are eliminated. Respironics* Integrated heated humidifier will be used if needed and set to an initial setting of 2. During the course of the night, this setting can be changed to optimise participant comfort. This study shall be interpreted by the co-investigator to determine the optimal CPAP setting. A successful titration will be defined as an AHI < 10.0 /h under the determined optimal pressure. Subjects in whom CPAP does not adequately treat OSA during the titration will be excluded.

Following the CPAP titration study, subjects will be randomly assigned to one

night of APAP and one night of fixed CPAP delivered by the Philips Respironics Sleep Therapy Auto System on consecutive nights in the Sleep Laboratory by the PSG technician with full PSG monitoring. The therapeutic pressure from the CPAP titration study will be applied on the fixed CPAP night and the APAP system will be allowed to determine the PAP level on the auto night.These studies should be performed within 14 days of the CPAP determination study. Humidification will be standardised at the level from the CPAP determination study. The same interface will also be used on each occasion.

At the conclusion of the subject*s participation in this study, they will be treated for their sleep disordered breathing condition per their physicians* instructions

Intervention

Subjects will be randomly assigned to one night of APAP and one night of fixed CPAP delivered by the Philips Respironics Sleep Therapy Auto System on consecutive nights in the Sleep Laboratory using full PSG monitoring.

Study burden and risks

We believe that the risks of providing positive airway pressure therapy with the Philips Respironics Sleep Therapy System are no greater than the risks encountered with other PAP devices. We believe that no significant risks will be posed to the subjects participating in this protocol, as the study is non invasive and will be conducted in a standard sleep laboratory and monitored by trained clinical staff. The PAP equipment has been tested to ensure safety. Should the auto CPAP equipment not perform as designed, therapy could increase or / and decrease more than desired. This effect could be uncomfortable or awaken the subject.

Additionally, a trained sleep technician / technologist will always be present monitoring the subject while the device is in use. The sleep technician / technologist will intervene should any problems be identified. The patient can also easily remove their interface device should it become uncomfortable or make breathing difficult. Rarely there may be skin irritation in response to the tape used to attach some of the electrodes. Other potential side effects of PAP therapy may include: ear discomfort, conjunctivitis, skin abrasions due to non-invasive interfaces and gastric distension (aerophagia), all of which are quite uncommon. Thus, we believe that the risks and discomfort associated with participation in this study are minimal.

There are a number of minor risks and hazards associated with the investigational device that do not differ from other positive airways pressure devices that provide positive pressure ventilation and/or its accessories (i.e., nasal masks, tubing, etc.). These include:

• pneumothorax*
• nasal passage irritation or dryness
• irritation of the eyes
• headaches
• upper airway contamination
• re-breathing of expired air if the mask is worn and the unit is not powered up
• hypotension secondary to a decrease in cardiac output

(*Note: the occurrence of a pneumothorax will be considered a serious adverse device effect, but has never been reported during studies of this type.)

Potential Benefits - Subjects will receive no direct benefit from participating in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. AHI > 15 confirmed (> than 50% obstructive events) by full PSG within last 14 days
2. Age >= 21 years of age,
3. Able to provide consent
4. Able to follow the instructions given by the investigator regarding using their CPAP device and their participation in this study

Exclusion criteria

1. Inability to tolerate CPAP during the daytime CPAP session
2. Failure of CPAP to adequately treat OSA during titration (AHI >= 10.0 /h under the determined optimal pressure)
3. PAP therapy is otherwise medically contraindicated: acute upper respiratory infection, encephalitis, sinusitis or middle ear infection or surgery of the upper airway, nose, sinus, or middle ear within the previous 90 days.
4. Untreated, non-OSA/CSA sleep disorders, including but not limited to; insomnia, Periodic Leg Movements (PLM) / Restless Legs Syndrome (RLS)
5. Intake of central relevant drugs, sedatives, or other drugs which impair sleep
6. Previous exposure to positive airways pressure therapy.
7. Acute dermatitis or other skin lesions or trauma interfering with the application of a mask
8. Unwilling to participate in the study.
9. Participation in another clinical study in the past 4 weeks
10. Shift worker
11. Other major medical disease/disorder that, at the discretion of the PI, renders the subject inappropriate for this study.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2011
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Generic name:	System One RemStar Auto A-Flex
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-11-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ISRCTN	ISRCTN19824122
CCMO	NL34864.060.11