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System One™ study: evaluation of the System One™ REMstar® Auto A-Flex for the treatment of obstructive sleep apnoea (OSA)

Submission date 24/11/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 14/01/2011	**Overall study status** Completed	
Last Edited 14/01/2011	**Condition category** Respiratory	

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
EAME09PRSTS01

Study information

Scientific Title
Evaluation of the System One™ REMstar® Auto A-Flex for the treatment of obstructive sleep apnoea (OSA): an international, randomised, controlled, crossover trial

Acronym
System One™ study

Study objectives
1. Automatic positive airway pressure (APAP) delivered throughout the night by the System One™ REMstar® Auto A-Flex, to subjects with obstructive sleep apnoea (OSA) is as effective as fixed continuous positive airway pressure (CPAP) delivered by the same device
2. The breathing event output (total and by epoch) from the System One™ REMstar® Auto A-Flex will result in a number of events (clear airway apnoea, obstructed airway apnoea, hypopnoea, apnoea hypopnoea index [AHI], respiratory effort related arousals and Cheyne Stokes Respiration) that is in agreement with those obtained from a full clinical polysomnography (PSG).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Currently being applied for in Denmark, Netherlands and France

Study design
Multicentre randomised controlled crossover group trial

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 contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Obstructive sleep apnoea (OSA)

Interventions
Following the CPAP titration study, subjects will be randomly assigned to one night of APAP and one night of fixed CPAP delivered by the System One™ REMstar® Auto A-Flex 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.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Apnoea-hypopnoea index (AHI)

Secondary outcome measures
1. Nocturnal oxygenation (SpO2)
1.1. Total time spent less than 90%
1.2. Lowest SpO2 during the night
1.3. Average SpO2 during the night
2. Total sleep time (TST)
3. Sleep efficiency (SE) %
4. Sleep architecture:
4.1. Min/% Non-REM sleep
4.1.1. Min/% N1
4.1.2. Min/% N2
4.1.3. Min/% N3
4.2. Min/% REM sleep
4.3. Min/% wake after sleep onset (WASO)
4.4. Arousals
4.4.1. No. of arousals/awakenings (all cause)
4.4.2. Arousals due to periodic limb movements in sleep (PLMS)
4.4.3. Arousal Index (AI)
4.4.5. Arousals due to respiratory disturbance (RDI)
5. Average pressure outputs
6. 90% pressure outputs

Overall study start date
04/04/2011

Completion date
19/10/2012

Eligibility

Key inclusion criteria
1. AHI greater than 15 confirmed (greater than than 50% obstructive events) by full PSG within last 14 days
2. Age greater than or equal to 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

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Inability to tolerate CPAP during the daytime CPAP session
2. Failure of CPAP to adequately treat OSA during titration (AHI greater than or equal to 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 Primary Investigator (PI), renders the subject inappropriate for this study

Date of first enrolment
04/04/2011

Date of final enrolment
19/10/2012

Locations

Countries of recruitment
Denmark

France

Netherlands

Study participating centre

Département de Pneumologie
Angers
France
49033

Sponsor information

Organisation
Respironics International Inc (France)

Sponsor details
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Sponsor type
Industry

Website
http://www.respironics.com

ROR
https://ror.org/05jz46060

Funder(s)

Funder type
Industry

Funder Name
Respironics International Inc (France) - an Activity of Philips, 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