

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	☒ Prospectively registered ☐ Protocol
Registration date 14/01/2011	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 14/01/2011	Condition category Respiratory	☐ Individual participant data ☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Multicentre randomised controlled crossover group trial

Study type(s)

Treatment

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(s)

Apnoea-hypopnoea index (AHI)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Respiroics International Inc (France)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

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

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration