

Treatment by uninterrupted positive airway pressure by nasal route - Evaluation of REMstar® Auto with C-Flex in clinical practice

Submission date 29/09/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/11/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/11/2008	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof J Meurice

Contact details

Service de Pneumologie
Cité Hospitalière La Milétrie
BP 577
Poitiers
France
86021
meurice@chu-poitiers.fr

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Study objectives

REMstar® Auto with C-FLEX is as effective at reducing the apnoea-hypopnoea index (AHI) in sleep apnoea/ hypopnoea patients as continuous positive airway pressure over 30 days when used in the home environment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Committee for Protection of Human Subjects, Poitou-Charentes (Comite Consultatif de Protection des Personnes dans la Recherche, Biomedicale de la region Poitou-Charentes), approved on 20/10/ 2005 (ref: 05.09.17)

Study design

Randomised crossover trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Sleep apnoea/ hypopnoea syndrome

Interventions

Participants were randomly allocated to the following two arms:

Arm 1: REMstar® Auto with C-FLEX over 30 days

Arm 2: Continuous positive airway pressure over 30 days

The intervention was followed by a 7-day washout period, and then the participants were crossed over to 30 days on alternate arm of study.

Intervention Type

Other

Phase

Phase IV

Primary outcome(s)

1. To determine if the REMstar® Auto in C-Flex mode is as effective as constant positive airway pressure on reducing the AHI of sleep apnoea/ hypopnea patients when used in the home environment. This will be assessed by data obtained during polygraph recording via the Stardust® device at the beginning and end of each period (30 days, 7-day washout then 30 days on alternate arm of study) and between each mode of use. This relates primarily to the following:

- a. AHI index
- b. SaO2 night (minimum, maximum and SaO2 95)

2. Data from the REMstar® device at the beginning and end of each period and between each mode of use. This relates primarily to the following:

- a. Maximum pressure
- b. Minimum pressure
- c. Average pressure
- d. Average number of hours use on nights used
- e. AHI index

Key secondary outcome(s)

1. To compare the clinical benefits and preference of patients between the REMstar® Auto in C-Flex mode versus conventional fixed pressure. This will be assessed at the beginning and end of each period and between each mode of use.
2. Quality of life and daytime alertness will be assessed by the Functional Outcome of Sleep Questionnaire (FOSQ) and the Epworth Sleepiness Questionnaire (ESS). Timepoints: Baseline (before first mode of use), after first mode of use is completed and after the second mode of use is completed.
3. A visual analogue scale will be completed by the participants at the end of each treatment period to assess daytime alertness

Completion date

13/03/2008

Eligibility

Key inclusion criteria

1. Male adults >18
2. Index of apnoea/ hypopnoeas >30/hour
3. Able to provide written consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Male

Key exclusion criteria

1. Past experience of treatment with positive airway pressure or non invasive ventilation
2. Participants who require 2 levels of pressure for nocturnal alveolar hypoventilation linked to a co-morbidity (obesity, hypoventilation, chronic obstructive pulmonary disease [COPD]) of sleep apnoea/ hypopnoea syndrome
3. Participants that have undergone surgery for the treatment of sleep apnoea/ hypopnoea syndrome, snore or tumour in the last 6 months or after their polysomnography (PSG) diagnosis
4. Tracheostomy

5. Respiratory infection, sinusitis or internal ear infection
6. Dermatitis or other facial lesions preventing the application of a mask
7. Unable to give written informed consent
8. Participants unwilling to volunteer
9. Unstable medication
10. Participants presenting with clinically significant COPD or unstable cardiac insufficiency
11. People benefiting from a reinforced protection will not be included in this study. This refers to subjects protected by law, persons accepted in a health or social establishment, private individuals of freedom by a court or administrative order, ill in urgent situation, and persons hospitalised without consent.
12. Participants should not have participated in a trial in the 3 months preceding or following the study

Date of first enrolment

06/10/2005

Date of final enrolment

13/03/2008

Locations

Countries of recruitment

France

Study participating centre**Service de Pneumologie**

Poitiers

France

86021

Sponsor information

Organisation

Respironics International (France)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Respironics International (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration