

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

<b>Submission date</b> 29/09/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/11/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/11/2008	<b>Condition category</b> 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

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

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

## 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 measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

06/10/2005

### **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

### **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Male

**Target number of participants**

20

**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)

## Sponsor details

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## Sponsor type

Industry

## Website

<http://global.respironics.com>

## ROR

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

# Funder(s)

## Funder type

Industry

## Funder Name

Respironics International (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

